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GENOME RESEARCH IN MEDICAL AREA AS A PERSPECTIVE DIRECTION FOR BUSINESS DEVELOPMENT ON RUSSIAN MARKET

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Abstract

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The aim of this research was to determine the potential of the Russian genome sequencing market on the basis of the new generation sequencer methodology. The author of this research took into account the theoretical data on the international development of the market for medical purposes and conducted a review of existing trends of development on the Russian market. Macro environment analysis was made on the base of PEST model.

As part of the research, the system of trading of Russian state institutions in recent years has been carried out. Also expert assessments about market development, opinions of ordinary people and their preferences have been found out through interviews and e-polls. In addition, the analysis of the company's existing distribution network was made by interviews with their representatives to predict the possibility of promoting a new product through an established distribution network.

The results of this research were the attempts to predict the demand for genome tests and market size of equipment for genome research under the influence of various factors and recommendations for Case Company for starting development and launching commercial activities in the genome sequencing market in Russia, in particular for medical diagnostic purposes.

Keywords: genome test, genome sequencing Russian market, new generation sequencing, sequencer demand market, genome test demand, sequencer, PEST model.

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1 INTRODUCTION

Science and technology development in modern life occupies an important place in all areas of people's activity. Especially it applies to the medical sphere, which is the most important for the person and his life. In medical field in the world have begun to develop personal genomics - as a science and as a field service niche for business and start-ups. Traditionally, doctors base their findings on observations, including on the symptoms of diseases. However, traditional methods are not always the most effective, since each patient has unique genetic characteristics. The opportunities that have emerged from the development of medical genetics have made it possible to understand in more detail the influence of genetic features and factors on disease processes. (Ku, Loy, Salim, Pawitan, Chia 2010, pp. 403-415.) Genomics section associated with the sequencing and analysis of the human genome.

Definitely it is a trend towards the development of this area, but at the cost of technology development and appropriate equipment is quite expensive. In Russia there are a lot of Special Institutes and scientific centers which have studied topic of genetic, but in usual hospitals and clinics such test are rather seldom or quite expensive. So many commercial companies are not engaged in this direction, because it is not clear when these tests will have a mass character in Russia and will be able to generate real profit (Suvorova 2015).

The task of medical genetics is to identify, research, prevent and treat of genetic diseases and the ways to prevent the harmful effects of environmental factors on human heredity.

Last several years in Russia has been a policy of import substitution, and government encourages the development of domestic production. In Russia have started a lot of manufacturers, some foreign factories are moving their production to Russia in order to avoid the loss of the Russian market. (Timoshenko 2015.)

Area of Genetic medicine and in particular the study of the genome is the most important milestone for the public health application of genomics and genetics, decipherment of the human genome. However, this topic is not fully researched the present day. Brought to a fairly substantial overall picture of the human genome structure and the role in it of nucleotides, their sites and sequences, their functions and interactions. Due to deciphering the genome it has become much easier and cheaper to

detect a tendency of various diseases, both hereditary and non-hereditary (Phillip & Pavel 2010).

From the viewpoint of science, the topic is deeply interesting and has a great future. Genome Research is widespread in the USA and is part of the insurance program. But such studies are rather expensive and in Russia from a commercial point of view, are not yet widespread. But from another side Market genome-sequencing in Russia annually increases an average of 15%. For research information on 2016 the market volume is estimated to be more than 2.5 bln. Rubles. (Yashina & Malacho 2015, pp.49-55.)

Case company has idea to develop this area and they started to collect information and market research of equipment, technologies and test systems for Genetic medicine. But there are questions whether be interesting from commercial side. If only few tests are made in this area daily, there will be no real market for such equipment and devices.

1.1 Case company

Case company Corwai LTD. is situated in Russia and at the moment is official sales distributor of foreign manufactures of medical devices and equipment from China, Estonia, Poland and Italy. Main area of company activity is laboratory and diagnostic area of medicine. The head office is located in St. Petersburg; also the company has subdivisions in Moscow.

The company is engaged in complex supply of equipment and medical devices in state and private laboratories; mainly it is biochemistry, hematology, urine analyzers and tools for the collection and storage of samples of biological materials, such as vacuum blood collection tubes, automatic lancets for getting capillary blood, containers for urine and other products.

Sales policy is the following:

- Direct sales in hospitals and clinics in Moscow and Saint-Petersburg (through tenders or direct contact with medical institutions);

- Distribution network in regions of Russia. In Figure 1 is available the distribution geography of the distribution network of Case Company.

Figure 1. Geography of Corwai's distribution network

Not so long ago the company began to develop additionally the sales of polymerase chain reaction (PCR) equipment, reagent sets and materials. Company start this direction as sales distributor of foreign manufacture, but have their own manufacturing possibilities to follow this project as local Russian manufacture for get preferences from Russian government.

The direction of PCR is also based on the study of the DNA of the human. It is a high-precision method of molecular genetic diagnosis that allows identifying a variety of infectious and hereditary diseases. PCR is a method that allows finding a small piece of genetic information (DNA) of an infectious agent, various malignant neoplasms and the definition of genetic to various diseases in the clinical material under investigation and multiplying it multiple times. Amplifying DNA during few hours can make identification and multicasting of a certain DNA sequence in billions of times. (Garibyan & Avashia 2013, pp. 2-4.)

PCR research is a popular and relatively cheap method in Russian market and used widely for infectious determination, such as HIV, Tuberculosis, Chlamydia and other. In the field of diagnosis of cancer, PCR research makes possible to establish a diagnosis at an early stage of the disease, to estimate the prognosis, and subsequently the quality of the therapy. According to the company's observations in the Russian market American and local Russian manufacturers widely distribute equipment and reagent

kits.

But PCR research method allows only to compare a person's DNA with a primer - that is, a causative agent, and tell whether there is a coincidence or not. Many tests are performed only with a response yes or no; some provide quantitative indicators of the "pathogen" in human DNA. An all-round understanding of the human genome and its peculiarities allows doing more complex genome sequencing technologies.

1.2 The general essence of the method of genome research

Genetic analysis of DNA is a study of the human genome for diagnosing and determining the individual risk of developing diseases and the tolerability of drugs, as well as for obtaining data on genetic characteristics, inclinations and abilities of a person. Each person has a unique set of genes (genotype), which determines his individuality and predisposition to a particular disease. (Ershov 2015.)

During the sequencing of the genome (or genome research) a researcher or clinical specialist receives information about all DNA which was found in the 23 chromosomes of human cells that contain about 3 billion pairs of nucleotides. This information includes sequences of all genes (20,000) and non-coding regions (which constitute the largest part of the human genome and participate, in particular, in the regulation of gene work, but the functions of the noncoding portion of the genome are still to be determined). Thus, as a result of one study (sequencing) of the genome, it is possible to obtain a huge array of information that will be used in clinical practice, both with the already available data, and with the data that scientists will receive as scientific progress in the future. (Sukchev 2013.)

1.3 Objectives of the study

Main aim of this Master's Thesis is to understand how genome research will develop in Russia on macro level and how it will be interesting from the standpoint of commercial activity. The main indicator is the number of tests that will be carried out with the exception of factors of external influence and the quantity of equipment that is used for such tests. The findings of this research will allow the company to make a decision about the feasibility of investments and time in this area for business development.

Research question: forecasting of demand of Genome Research on Russia market from commercial point of view.

Sub questions:

- What are conditions of the market: demand, customers, competition and other business environment factors?
- Political and economic forecast for Genetic Medicine in Russia and law regulations.
- Customers' opinion about the potential product and prospects of it on the market from various angles.
- Knowledge, expectations and readiness of ordinary people for the topic of genome research.
- The ability for Case Company to promote a new product through an existing network of distributors.

1.4 Definition of products for research

The study of the genome is worthy of an abstraction topic, which includes methodologies, scientific developments and practical use. Case company is primarily a trading and manufacturing company that works directly in the market of sales products. In this part it was defined products which are used for Genome research for medicals or research aim and can be produced and sold in reality.

The human genome consists of more than three billion of these nucleotides, which are located in a strictly defined sequence. Unfortunately, sometimes it happens that some nucleotides disappear or are doubled or replace one another. In many cases, this leads to an incorrect formation of the human health. This can manifest as congenital malformations or small developmental abnormalities, mental retardation, autism or other manifestations. (Nikolaenko 2012.)

Sequencing is a test for determining genetic damage (mutations) in DNA, which are the cause of hereditary diseases, hereditary predispositions or the peculiarity of the organism.

Determining the structure of the genome is not an easy task. It requires the isolation of DNA, its special processing (fragmentation, modification, amplification) and obtaining information on a special device - a sequencer. Full-genomic sequencing gives the most

complete set of data on the structure of genetic material and allows us to evaluate in detail all individual genetic variations. (Nikolaenko 2012.)

Products that are used for genome research begin with simple devices for collecting samples, equipment for DNA isolation and end up with IT systems for analyzing and outputting results. In the framework of this study, it will not consider products of general use, for example tubes for taking blood – because they can be used for other medical test too. The goal of this research will be precisely the sequencing of the genome. So it considered as products sequencers and reagents for them.

1.5 Phenomenon of the thesis topic

The topic of creating a new or innovative product is widely studied and described in books and researches. This information can be used for following study. From the other side there are a lot of researches of development areas in medicine in local and international sources. Usually these studies have scientific nature. Feature of this study will be to identify research scientific trends and make comparisons with real opportunities for manufacturing or possibilities for sales market.

Also the research should take into account the features of the local market. Because some product which is used, for example, in rich and modern European countries or the USA may not be interesting for Russian market.

The Thesis relates the perspectives of science development and the real possibilities of demand in this area for making decision about investment in the Genome Research direction. There is available information from the standpoint of scientific research institutes and from the standpoint of large companies already involved in Genetic areas, and as usual they said that it is a very perspective and in future there will be large demand.

But during speaking with practical doctors or visit some medical exhibitions there is little information about such products and the present Russian market relates to this topic as a far and expensive prospect. So the main goal is to compare the real possibilities of the market demand and scientific perspectives for a decision to participate in this direction or not.

1.6 Delimitations of the study

The study will include following points:

- Theoretical part based on the market research of new directions and tendency of development of Genetic medicine;
- Empirical part based on practical research, which will follow:
  - To analyze current market situation and possibilities of development;
  - To collect and analyze data from specialists.

The research will give recommendations for future research and economical calculation of the projects. This part will not be included in this study. But it will include first marketing review of market and tendency.

The Thesis will not include the research of Genetic and Genome topic as a scientific topic, there will be a short review of base technologies which are going to be analyzed as “product”.

The Genome research is carried out for the purposes of scientific research and samples can be taken not only from human biomaterials but also from animal, micro-borders and other. This Thesis will focus only on the human genome and its capabilities for research for medical purposes.

1.7 Structure of the thesis

In the first part, there is a description of the problem, the objectives of the research and a brief introduction to the essence of the study of genome test and description of the tasks of the Case Company in this work.

In second part is the macro environment analysis on the base of PEST (political, economic, society, technology) model of the international market, the current situation on the Russian market and it reveals the factors of influence on demand in the genome sequencing market and theoretical market forecasts. On the base of theoretical background are formed theoretical statements, which are later verified on the basis of an empirical analysis.

The third part describes the methodology for analyses, with a breakdown into the

analysis of secondary information and primary information. A methodology for collecting information from different groups of respondents and ways to analyze this information is also described.

The fourth section describes the results of the analysis of information using the indicated methods and the main results are laid out.

The fifth part is the formation of the author's conclusions on the basis of the analyses and forecasting of the market of sequencing based on the theoretical information and the data obtained from the empirical study.

In the sixth part, the author summarizes the results of the entire study, indicating the Company's recommendation on the tasks assigned, as well as recommendations on the possibilities for future research.

2 MACRO ENVIRONMENT ANALYSES

Today's business has reached a fairly high level of development, where priority is given to monitoring those factors that have a great impact on the successful development of the company. One of the main methods that are now used is the PEST analysis (Figure 2). This type of analysis is a marketing tool designed to identify the political, economic, social and technological aspects of the external environment that affect the company's business. (Bensoussan & Fleiser 2008, pp.161-177.)

For the study of factors that affect the market of genomic research will be made a complex analysis of external factors that affect the activities of business entities in this fields. The title itself contains the main areas that are being analyzed: politics, economics, society and technology.

The analysis is carried out according to the "factor-enterprise" scheme. The results of the analysis are formulated in the form of a matrix, which is subject to macro-environment factors; the predicate is the force of their influence, estimated in points, ranks and other units of measurement. The results of the PEST analysis allow us to assess the external economic situation in the sphere of production and commercial activity. (Basu 2004 pp.98-101.)

In this Thesis, the result of the PEST analysis will be evaluated in a text evaluation of

the influence of the factor, after a theoretical review and verification of theories based on the empirical research.

Figure 2. Structure of PEST analysis. (Bensoussan & Fleiser 2008, pp.161-177.)

2.1 Technological factors of influence on the market

2.1.1 Basic history of genome sequencing

The first method of sequencing, which scientists managed to use to process whole genomes (including the human genome), was sequencing by Sanger (Sanger sequencing) in 1977. For more than 30 years, until the 2000, it remained the main way to determine the sequence of any nucleic acid: it was this method (with minor modifications) that the human genome was read. (Obenrader & College 2003.) And until now, Sanger sequencing is the most accurate method, which is used to check the results of a new generation of sequencing if necessary. This method was used in global projects for sequencing the human genome, various animals, bacteria and viruses. However, this method was not suitable for rapid routine sequencing of human genomes for clinical purposes. Therefore, there was a need to invent new technologies for full genomic sequencing.

In 1990, the international program "Human Genome" was launched, in which separate sections of the pre-tagged genome for sequencing were isolated for each team from America, Europe and Japan (Speaker, Lindee & Hanson 1993 pp. 18-19). By this time,

several biotech companies, primarily Applied Biosciences, have learned to automate the sequencing processes of Sanger. One of the first who realized the possibilities of automation of sequencing was Craig Venter. In 1992, two years after the launch of the Human Genome Project, Venter organized his own institute (The Institute for Genomic Research), in which DNA sequencing was first put on stream. (Fridovich-Keil 2016.)

The cost of sequencing of both individual genomes by the time they were read in 2007 was about one million dollars. And this, of course, is significantly lower than 100 million in 2001, but still a lot: with such prices count on reading the genomes of hundreds or thousands of people or offering such a service to ordinary people would be impossible. (Muir, Li, Lou, Wang, Spakowicz, Salichos, Zhang, Weinstock, Isaacs, Rozowsky & Gerstein2016, pp. 3-4.)

However, fortunately, just at the moment when the reference genome was created, the technology that allows to "catch" individual differences in genomes is fundamentally simpler and cheaper than usual sequencing technology of DNA microchip (Johnson 2009). DNA microchips began to appear in scientific laboratories in the 90's, and in the mid-2000s the first companies appeared that offered analyses of the personal genome on their basis.

Today the genotyping technologies are losing their positions (speed and cost) and the era of the so-called new generation sequencing methods is starting. It is their appearance that has ruined the cost of the procedure from millions to thousands of dollars. (Ershov 2015.)

2.1.2 The technological development of genome research on international market

Full genome sequencing technology revolutionized medical diagnostics, academic laboratories and biopharmaceutical companies, and changed the structure of healthcare and applied markets.

In the USA sequencing has become a real sector of the economy, in a direct or an indirect form it involves about 300 thousand people. There were launched genomic projects in 2014, January 2015 and the US president proposed to allocate $ 215 million from the 2016 budget on the project of sequencing a million genomes of US citizens. (Yashina & Malacho 2015, pp.49-55.)

In the United Kingdom at the end of 2012, Prime Minister David Cameron presented the

"Strategy for UK Life Sciences - One Year One" program, which formulated a goal - to make the UK the world leader in genomics and bioinformatics. It details the main expected results and measures that the Government will take to achieve this goal. One such measure was the allocation of £ 100 million for the sequencing of 100,000 genomes of cancer patients and other patients. (Zubov 2012, pp. 2-15.)

In China in Beijing is also organized one of the most powerful centers of full-genomic sequencing. In 2017 the largest center for genetic research in the world, the Beijing Institute of Genetics (BGI), has announced the opening of two laboratories in the United States, which will be engaged in an ambitious project to create next-generation sequencing technology. China will try to get more efficient sequencing technology through cooperation than the one developed by the leading American company in this field “Illumina”. (Cyranoski 2016, pp.462-463)

In 2013, a new player from Saudi Arabia started a national network of sequencing centers for carrying out genomic sequencing of one hundred thousand of its citizens. (Zubov 2012, pp. 2-15.)

According to a report by Grand View Research, Inc., the genomics market in the world is estimated to reach USD 22.1 billion by 2020. The expected growth of market is 10.3% from 2014 to 2020. (Grand View Research 2016.)

In the last decade, sequencing technologies have developed at a very rapid pace, thus reducing the cost of each DNA base. Sequencing, which cost $ 3 billion a decade ago for the Human Genome Project, can now be done for thousands of dollars or less. (Gitschier 2010.) The first devices for sequencing were created, first of all, for scientific research. They had a reasonably low throughput and were not suitable for clinical studies. At present, platforms for DNA sequencing of the "third generation" have appeared and are actively developing. The third generation differs from the second in that the primary amplification of DNA is no longer required. The DNA under study is sequenced directly at the level of one molecule using specially designed polymerases. The advantage of this approach is that it is possible to avoid the problems associated with the accumulation of errors arising during the amplification of DNA. (Sukchev, 2013.)

In following Table 1 are noted major market players with short description:

Name of company	Country	Description of company
Illumina Inc.,	USA	Illumina, Inc. founded in April 1998, develops, manufactures and implements systems for analyzing genetic diversity and biological functions. Illumina produces a line of products and services for sequencing, genotyping and studying gene expression to carry out genetic studies necessary for medicine, genomics and proteomics. (Illumina)
Oxford Nanopore Technologies	United Kingdom	U.K.-based company founded in 2005 and is developing and selling nanopore sequencing products for the direct, electronic analysis of single molecules. (Oxford Nanopore Technologies)
Roche Diagnostics	Switzerland USA	Roche is one of the leaders in the healthcare market, one of the ten largest companies in the world in the field of pharmaceuticals and diagnosis of diseases. The main goal of Roche is the production and promotion of drugs developed on the basis of innovative technologies. The company was founded in 1896 in Basel, Switzerland, and today has offices in more than 150 countries and employs more than 70,000 people. (Roche) Roche Holding AG buys up companies and research centers in the field of medicine and has a very wide profile of activity from gene equipment to medicine drugs. (Roche)
Bio-Rad Laboratories Inc.,	USA	Bio-Rad Laboratories is a large manufacturer of analytical equipment, auxiliary devices

		and consumables for various biology and clinical laboratories. The company is constantly improving in the development of new devices. The producer achieved special achievements in the field of genetics. Under the Bio-Rad logo a whole line of devices for PCR, electrophoresis, proteomic analysis, gene transfer, including using the transfection method, is offered. (Bio-Rad)
Thermo Fisher Scientific Applied Biosystems™	USA	Thermo Fisher Scientific is an American multinational biotechnology product development company, created in 2006. Applied Biosystems (formerly NASDAQ: ABIO) is the original name of a biotechnology company founded in 1981 in Foster City, California, which was joined to the Thermo Fisher Holding. (Thermo Fisher Scientific)
Beijing Genomics Institute	China	The scientific center dedicated to determining the genomic sequence, headquartered in Shenzhen, Guangdong Province, China from 2008 year. (Researchgate)

Table 1. Major international players of genome research market

From the main review America holds the leading positions in the market of commercial sequencing. Also when studying the history of companies that are engaged in research in the field of sequencing and genomic development, it is interesting that companies are often change within the market – some famous companies bought up by large holdings.

For example, in 2010 Life Technologies Corporation acquired Ion Torrent, which developed semiconductor sequencing technology, for $ 725 million. In 2013, Termo Fisher Scientific Corporation acquired Life Technologies with all of its assets for $ 13.6 billion. The structure of the supply market is changing very rapidly, both in terms of the

technologies offered and the companies themselves, and the data very quickly become old.

Very instructive is the story of the company 454 Life Science Inc. that acquired corporation Roche. In 2005 – 2007 it was the best in the world pyro-sequencers company but did not withstand competition and in the middle of 2014 year was withdrawn from production. Approximately at the same time, the development of the Chinese pyro-sequencer BIGIS-4, which in all respects was not inferior to the Roche, was completed, but appeared too late. (Zubov 2012, pp. 2-15.)

In 2017, several promising developments in the field of new generation sequencing are presented on the market. These approaches are applied in sequencers of a new generation:

- Ion Proton and Ion Personal Genome Machine (Thermo Fisher Scientific) - technology of ionic semiconductor sequencing;
- MiSeq and NovaSeq (Illumina) - a technology for sequencing on molecular clusters using fluorescently labeled nucleotides;
- MinION, GridION X5, PromethION and SmidgION (Oxford Nanopore Technologies) - nanoporous sequencing.

2.1.3 Features of developing genome research technologies in Russia

In Russia, the development of NGS (next generation sequencing) technologies until recently was considered an impossible task due to the lack of experience in carrying out such applied works and limited financial possibilities. But at the same time in Russia the geography of attempts to develop sequencers of a new generation is very wide and includes:

- **Moscow** (LLC "Sintol", LLC "Rastr Technologi", LLC "Helicon Company", IMB RAS, etc.),
- **Novosibirsk** (IAE SB RAS, IHBMM SB RAS, IFP SB RAS, LLC "Biosset"),
- **Zelenograd** (OOO Gamma, LLC ElemInfo ", LLC" NANO VIZHIN ", JSC" NT-MTD ",

- **St. Petersburg** (IAP RAS,OOO NPK "Orion Medik"),
- **Protvino** (LLC "NPO DNA-Technology"),
- **Vladikavkaz** (LLC WTC "Baspik"),
- **Irkutsk** (LIN SB RAS), Ufa (IBG UNSC RAS / OOO Biofort),
- **Krasnoyarsk** (IIPiRE / OOO Vitim-LAB),
- **Chernogolovka** (ISSP RAS),
- **Dolgoprudny** (Carbonlite LLC),
- **Saratov** (SSTU)

In 2013, due to financial support from the Ministry of Education and Science of the Russian Federation and the Technology Platform "Medicine of the Future", the Institute of Analytical Instrumentation of the Russian Academy of Sciences, LLC "Sintol" and the Experimental Plant for Scientific Instrument Making of the Russian Academy of Sciences created the first Russian sequencer "NANOFOR 05". It is an open automatic capillary electrophoresis system with detection of laser-induced fluorescence. Technology which uses this analyzer is capillary and near to “Sanger sequencing” which was the founder of sequencers (Arustamova 2015, p.31.).

Despite the fact that this technology has already lost to sequencers of the second and third generation, this is widely used in the Russian market and in the world and there are a number of tasks that are solved with the help of these sequencers. According to experts, the Russian market of sequencers’ potential is no more than 1000 sequencers. The number of capillary sequencers is 85% of the total volume and is 200 000 - 300 000 analyzes per year. (Arustamova 2015, p.31.)

2.1.4 Highly skilled specialists

After the procedure for sequencing the genome, it is not available finished result but get a set of data that must be interpreted; decipher made by the biologists; interpretation made by bioinformatics. Biologist specialization is popular in Russia and there are a lot of such specialists. But the most difficult work is just the second - bioinformatics need, on the one hand, to know biology, on the other - programming. They have to decode the

genome, and it is difficult to find them: an ordinary programmer is hard at mastering molecular biology and vice versa. Professionals in this field will play a major role in the personalized healthcare practice because they are responsible for managing patient data. (Alzu'bi, Zhou & Watzlaf 2014, p.3.)

Figure 3 shows the sample of result of sequencing the genome using BrightDye (А), Bigdye (Б), which were provided by researchers from the Institute of Cytology and Genetics of the SB RAS, Novosibirsk and published in article "Reagents for sequencing by Sanger and much more from Nimagen in the 2015" on web site of Skygen company (Skygen).

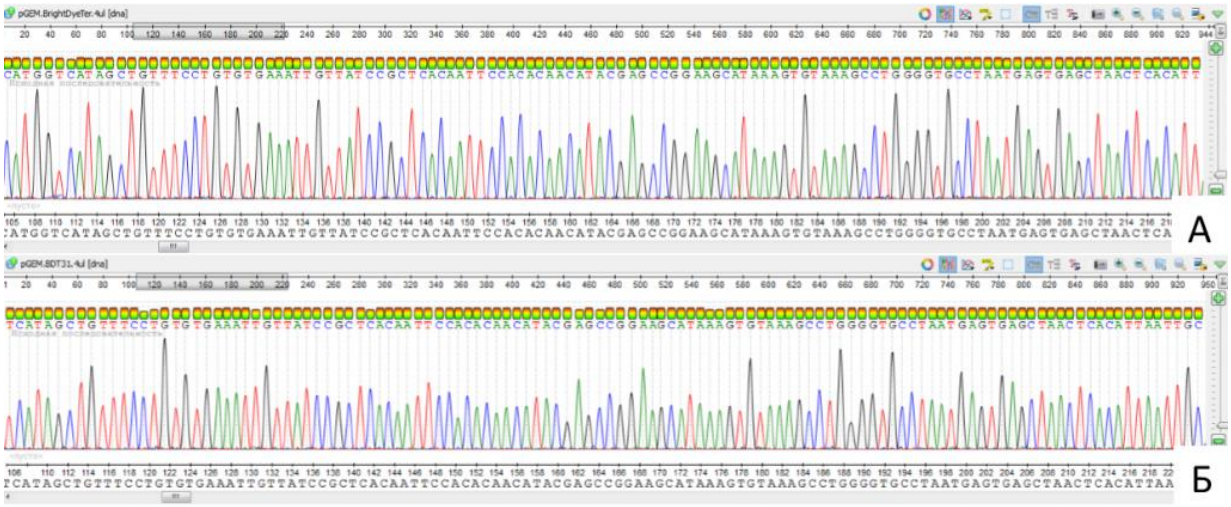


Figure 3. Sample of results from the genome sequencing

Results of the system do not give us a ready result with a description of the genome, of all the particular systems of man, his predisposition, and so on. Sequencing gives the specialist a set of "code" that must be interpreted with the use of high qualification.

2.2 Economic factors of influence on the market

2.2.1 Russian economic crisis

In connection with the Russian economic crisis of 2015 expenditures of the budgetary sphere are significantly reduced. The law on the budget, presented by the Ministry of Finance of the Russian Federation, assumes a drastic reduction in spending on health in 2017. Thus, in 2017 the government reduces medical expenses in comparison with 2016: in the specified budget of 2016 there was five hundred and forty-four billion rubles are spent for this purpose, then for 2017 only three hundred and sixty two billion rubles

will be allocated for same. From this “medical” budget money is going to send around sixteen billion rubles for medical research sector, which is a decrease compared to 2016 by 21%. (Obukchov 2016.)

2.2.2 Feature of health system financing

System financing health care area in Russian federation can be represented in the following Figure 2 created by the author.

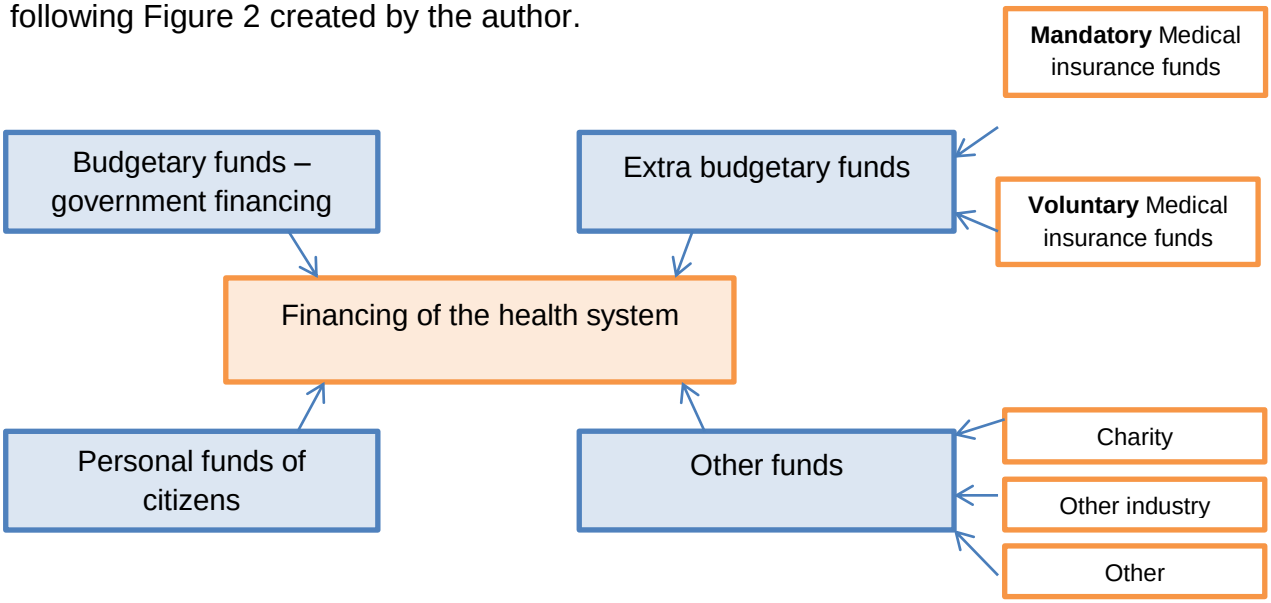


Figure 4. Financing of the health system sources in Russian Federation

The main newest challenge for the Russian healthcare system is the need to address the large-scale tasks of reducing the death rate and increasing the salaries of medical workers while reducing the size of government funding.

The most significant institutional changes in the sphere of health in recent years are associated with the modernization of the mandatory medical insurance (MMI), carried out in 2011-2015 in accordance with Federal Law No. 326-FZ of November 29, 2010 "On Mandatory Medical insurance in the Russian Federation". As a result of the restructuring of the compulsory medical insurance, there was a stabilization of financial flows in this system. In addition it is important that in different regions of Russia the nature of financing is very different. (Shishkin, Sazina & Selezneva, 2015, pp. 3-15.)

Despite the general trend towards strengthening the role of MMI in public health financing, there are still very large differences between regions. Moscow and Saint-Petersburg are historically the richest regions in Russia on budgetary financing and on the level of the overall economy. Legal entities pay taxes at the place of their registration. Many corporations in Russia, whose production activities are almost 100%

concentrated in the regions - nevertheless, have central offices and are registered in Moscow. Accordingly, all of their gigantic incomes, even taking into account optimization and tax evasion - still settle in a fair amount in Moscow for example.

Indeed, the main reason that Moscow and Saint-Petersburg have a solid budget is because of the tax component. The remaining regions are often financed from the federal budget, which is formed at the expense of donor cities. The regions-donors for 2016 became: Moscow, Moscow region, Leningrad region, Republic of Tatarstan, Sverdlovsk, Chelyabinsk, Tyumen regions, Nenets Autonomous Area, Khanty-Mansiysky Autonomous Area and Yamalo-Nenets Autonomous Area (Ivanov 2016).

2.3 Political factors of influence on the market

Policies and projections at the macro level in any case affect economic situations and micro-level behavior for specific companies and individuals. When starting a project, it is important to take into account not only internal indicators and metrics, but also analyze the opportunities and risks associated with the country's behavior in domestic policy and relations with other countries.

Now Russia is in a difficult and interesting situation because of the sanctions and the attitude of Europe and America. On the one hand it is bad, but on the other hand such situation has given opportunities for the development of some business in Russia. (Lipman & Petrov 2010.)

2.3.1 The modernization program

In 2011 in Russia was in operation state modernization programs of the Ministry of Health. Many laboratories purchased equipment in 2011-2012 of which now many are outdated and their least exploitation is not favorably. Thus, the equipment fleet in Russian institutions is outdated in terms of technology and also the cost of research. New developed equipment and devices allow making technology of genome research cheaper. The cost of sequencing the same amount of material at the second and third generations differs at times. As a result, all previously purchased by Russian centers sequencers of this series have aged both morally and economically.

2.3.2 Sanctions and import substitution

The sanctions imposed on Russia by a number of Western countries, and the Russian

government's response, have had a stimulating effect on import substitution in the economy. Import replacement in 2017 is within 30%, which means that all goods, products, as well as services produced in Russia, account for only 30%, the rest has to be bought abroad. By the end of the year, this figure may decrease, but not due to an increase in the production of domestic goods, but due to a decrease in imports, which will lead to the formation of a deficit in the country. (Aris 2017.)

According to analysts' forecasts, the most promising sectors for import substitution at the moment are:

- Machine-tool construction;
- Heavy engineering;
- Textile production;
- Electronic industry;
- **Medical production;**
- **Pharmaceutical production;**

Perhaps nowhere has the idea of import substitution caused so much concern, as in the field of medicine. Under the sanctions introduced in 2014 were more than 100 different positions, from medicines to specialized medical equipment. But a lot of drugs, diagnostic equipment and other things were almost completely provided with goods of foreign production.

Today, the state program of import substitution in the medical sphere includes more than 200 projects, most of them already developed. Only in 2016 in support of manufacturers about 15 billion rubles were allocated from the budget (Neverova 2016).

To stimulate production, free special economic zones (SEZ) are actively developing. The world's largest experience in the creation of the SEZ belongs to European countries. Special economic zone is a territory that has a special legal status, on which preferential economic conditions for the performance of activities for Russian or foreign entrepreneurs operate. Residents of such zone have special tax conditions, custom clearance conditions, land infrastructure (water, electricity connection) and low cost of land purchase. But in order to be located in such a zone it is necessary to prepare a

business plan for the project, protect it and get state support. (Schneider 2015, pp.4-6.)

Russia has a serious potential for the operation of SEZ, which now has 25 such zones in different directions. For production of medical product it can be applied:

- 6 industrial special economic zones (SEZ PPT Alabuga, Togliatti, Lipetsk, Mogilino, Titanium Valley, Lyudinovo);
- 5 technological zones (SEZ TVT Dubna, St. Petersburg, Zelenograd, Tomsk, Innopolis).

2.3.3 Tender (auction) regulation

In addition to stimulating domestic production through funding and project grants, the Russian government also applies restraining measures. Federal Procurement Law (44-FZ) and Resolution No. 102 list medical products, which were manufactured in foreign countries that may not be bought by state-owned companies if at the same time at least two equivalent domestic medical products are offered. When making purchases of medical equipment, devices or reagents through state tender if an application there is more than two offers of “domestic” manufacturers ("domestic" goods means goods which are produced in Russia, Belarus, Kazakhstan, Armenia, Kyrgyzstan) foreign goods cannot take part in this tender. If in the auction there are one “domestic” and a foreign participant, the tender will go in usual way but if the winner is a participant who offered goods of foreign origin in the application, then the contract is concluded at a price 15% below its price offer. For example, a participant who offered a price of 1 million rubles during the auction, but if a product of foreign origin is offered in the bid, the contract will be concluded at a price of 850 thousand rubles. (Heidemann 2016.)

These laws have strongly influenced the purchasing market in Russia. The market of medicine services in Russia is overwhelmingly composed of state in comparison with commercial centers. For example, in 2016 Case Company made a research about market of vacuum blood tubes which are used in laboratory and compared the share of state buyers and commercial and concluded that 80% of all purchases are made by public tenders and only 20 % by private clinics.

2.3.4 Features of production localization

In these conditions, Russian companies began to move the place of production from abroad to Russia. In the early years there was a very interesting trend - while the Russian government did not fully determine the criteria for localizing production many companies brought the product from abroad and made a very small part of the technological processes in the territory of the Russian Federation and claimed that it is “domestic” product.

The Russian government is discussing the possibility of modernizing the domestic economy, pursuing a policy of import substitution through localization, which means the placement of production in the territory of the Russian Federation originally of foreign origin.

For medical products were established criteria for recognition of products localization:

- The share of imported components in the final cost of a medical device should not be more than 50%.

  In addition, it is necessary to ensure:

- The required volume of technological operations
- The presence of rights to technical / engineering / engineering documentation in the amount sufficient for production, modernization and development related products
- Requirements for development or design
- Requirement of availability of service

To confirm these requirements, company should receive a certificate CT1 in the Chamber of Commerce on a fee basis. (Chamber of Commerce of the Russian Federation)

2.3.5 Registration

Equipment and devices for genome research can be used in several directions:

- clinical practice
- research activity

If equipment is used for clinical practice, it is medical product. All medical products (equipment, devices, reagents, software) traded on the Russian markets should be registered in Roszdravnadzor - The Federal Service for Supervision in the Sphere of Social Development and Health, which is an executive body whose main task is supervision and control in the field of health and social development. This registration must be obtained regardless of where the equipment is used - in public hospitals or in private clinics. Registration of foreign products will also be checked during customs clearance when imported into the country. For state hospitals and tenders products without registration will not be allowed in the tender. If the private clinic uses the products without registration, then Roszdravnadzor has the right to inspect and issue significant sanctions right up to criminal prosecution. (RF Government Resolution from December 27, 2012 N 1416, 2017).

If the genome tests are made for research activity, then, on the one hand, the requirements are slightly weaker, but laboratory (or institute) should have status (and resolution) of scientific and research Institute. In this case, the tests cannot be applied to medical purposes, but only as research and have a recommendation character.

The issue of registration of medical products is now very acute in Russia. By experience of Case Company, for last 3 years the procedure for registering a medical product - even the simplest one - takes from 1 to 2 years. These terms include the preparation and updating of the product dossier, the conduct of toxicological and clinical test and documentary procedures. In case of refusal at some stage, even because of a small error in documents, files and papers, company can roll back several stages and increase the registration time. According to the companies' feedbacks in the Russian market, the problem of registration concerns not only foreign manufacturers, but also is similar for local manufacturers.

There are also problems in the registration of high-tech products, such as the product considered in this Thesis. Usually, clinical trials are conducted in comparison with

products already registered in the market and an assessment of compatibility is made. When registering a fundamentally new product, additional difficulties arise in the methods of evaluation and the methods used - which only delays the time of registration. (Astapenko & Sukhanova 2016.)

Questions from representatives of the professional community also cause insufficient number of experts in the country who are able to understand the specifics of the whole range of medical equipment; term of waiting for a response when submitting documents for registration of medicinal products; the need to maintain a staff of highly qualified technical staff who deal exclusively with registration issues of medical product; the incommensurably high costs of registration – around 600 000 rubles for one item, from which the smallest enterprises suffer most, which because of this are forced to cease their activities. (Denanova, Vilensky & Agups 2014).

As it is clear from the chapter about the description of sequencing technologies, these technologies are developing very rapidly and the equipment is rapidly becoming obsolete - it is possible that while the company registers two years the equipment and reagents, sequencing technologies will go ahead and registered analyzer in two years will be already obsolete.

So the development and modernization of medical facilities are largely constrained by the administrative barriers. This question often and actively rose at many thematic conferences. In August 2017, the first meeting of the working subgroup on the development of high-tech medical products of the expert council for the development of biotechnology, pharmaceutical and medical industry was held at the State Duma Committee on Economic Policy, Industry, Innovative Development and Entrepreneurship. Experts suggested simplifying the rules for registering medical products. (Zdrav.expert, 2017.)

Participants of the meeting came to the conclusion that the introduction of international practice in Russia on the declarative form of confirmation of compliance of medical facilities with the required parameters in case it already has a registration certificate would help to remove a number of problems when registering high-tech medical products. (Zdrav.expert, 2017.)

All the described factors affect the development of the medical sector in general and the development of genomic sequencing in particular and should be taken into account,

when predicting the development of this direction in the future.

2.4 Social factors of influence on the market

The main deterrent to the active development of Russian genome research market (direct-to-consumer) segment is the low awareness of society, the population about the modern possibilities of genetics and its accessibility. Many people think that genetics is a purely scientific discipline, without any practical significance. The knowledge about what opportunities genetics gives in terms of personalized medicine are almost absent from medical personnel.

Therefore, in itself, the genetic test is still an entertaining and cognitive product for the premium audience. To translate its effect from entertainment into a practical field, consultations of specialized doctors, additional analyzes, recommendations of professional nutrition experts and other aspects of the lifestyle are needed. (Rusbase, n.d.)

For research and work with the results of genetic analyzes, their data need to be stored somewhere, and today in the world there is an active process of accumulation and storage of genomic information in large databases - biobanks. The creation of such storage facilities is primarily related to the need to conduct medical research and diagnosis of deadly diseases, which require an increase in the scale of the data under study (Eropkin 2015). For maximum accurate comparisons, scientists and/ or medical professionals need the largest possible base of DNA samples. The social issue as a defense has only just begun in Russia.

2.5 Russian market review

2.5.1 Market of equipment and materials

Prospects of the world market are very promising, but Russian market does not look so rosy. According to a research in 2015 the market of full genomic sequencing in Russia annually increases an average of 15%. At the same time, the market volume is estimated at more than 2.5 billion rubles. The main part is the equipment market, the volume of the market for consumables is very small and the number of installed high-performance analyses more than 120 units. (Yashina, Malacho & Sorokoletov 2016, pp.182-186.)

Researchers Yashina and Malacho (2015) made a study of the market sequencing based on government and commercial purchases. In Table 2 is information from state trade system about volumes of purchases.

Year	State contract, rubles	Commercial orders, rubles	Total, rubles
2010	511 162 000	No data	511 162 000
2011	2 211 566 000	No data	2 211 566 000
2012	2 509 868 000	87 000	2 509 955 000
2013	2 135 698 000	187 535 000	2 323 234 000
2014	2 145 732 000	232 975 000	2 378 708 000
2015 (6 months)	1 345 843 000	177 091 000	761 467 000

Table 2. The volume of the Russian market calculated by the amount of contracts (Yashina & Malacho 2015, p.183).

Foreign companies dominate the market, and the composition of has not changed during the last few years. The world and the Russian markets are monopolized by several large companies (Illumina, Thermo Fisher, Roche, Qiagen), expanding their sphere of influence is due to acquisitions of smaller research projects.

Organizations purchasing equipment are roughly divided by belonging to the Russian Academy of Sciences and the Ministry of Health. By geographic principle, the bulk of the equipment is in The Central Federal District, Moscow and St. Petersburg, in less remote regions (Murakhovsky 2016).

2.5.2 Service commercial market

High-performance sequencing methods have been developed since 2006 and allow to read the complete human genome in a few days. It costs around 2000 dollars. It is possible to read only the protein-coding part of the human genome, the so-called "exosis", which is of interest to clinicians (a doctor working in a clinic engaged not only in medical practice, but also with scientific observations and research). This process takes less than one day and costs 500-600 dollars. Such technology of exom reading is

now more often used in clinical practice in Russia. (Afanasev n.d.)

Over the past years, methods of genetic analysis, approaches to medical genetics and genomics have become much more understandable and accessible to the mass consumer. Medical clinics and start-ups offer services based on genetic analysis, in Russia this market is also growing and developing. Not only are end users interested in genetic technologies, but also corporations and states. (Krauzova 2016.)

According to a publication on web site Rusbase “Genetic tests in Russia: players, problems and trends” opinions about the market of the player-based commercial sector became available. Rusbase is an independent on-line publication on technology and business, event organizer and service provider for entrepreneurs, investors and corporations.

Sergey Musienko - Director General of Biomedical Holding "Atlas" said in an interview that a complex genetic study carried out in 2016 in Russia including about 20 thousand people, which indicates the early stage of the emergence of the market (Rusbase).

The segment of the market for the diagnosis of rare hereditary diseases is about 200 million rubles a year. Segment of tests for predisposition to multifactorial diseases - personal genetics - about 100 million rubles. Growth rate is about 20-30% per year. This information was announced in 2016 by Valery Ilyinsky, CEO of the Genotek. (Rusbase)

Vladimir Volobuev - Managing Director and co-founder of MyGenetics noted that MyGenetics works in the segment of direct-to-consumer DNA tests (when a person receives and uses the results of DNA research independently, without recourse to outside specialists). According to estimates, the volume of this segment currently in Russia is 300-400 million rubles, the annual growth of the market is 20-25%. (Rusbase)

2.6 PEST matrix and theoretical statements

Table 3 summarizes the results of the PEST analysis of the theoretical information on the basis of the theoretical knowledge obtained from the literature and published articles. And Table 4 contains more detailed description of some conclusions or opening questions, related to research questions that will be analyzed during the empirical part.

POLITICAL	**ECONOMIC**
- import substitution policy; - long registration at the state level; - weak development of domestic new products	- economic crisis; - features of financing; - not including gene therapy in the medical program; - high cost of tests;
SOCIAL	**TECHOLOGICAL**
- not informing the population about new opportunities; - unavailability of the system to protect information about genome research.	- rapid technological development; - fast obsolescence of old technologies; - inexpediency of using old technologies; - requirement of special personnel of bioinformatics;

Table 3. PEST matrix of factors of influence on the development of genomic direction

№	PEST group	Statement	How and why it is planned to open a topic in the empirical part
1	Technology	**International market development** The market for personalized medicine is very promising at the international level and as a consequence there is growing interest in genomic research, especially taking into account the cheapening of technology of new generation sequencing methods. International market plan to increase an average of 10.3% to 2021 year (Grand View Research 2016.)	To understand the development of the market, it is necessary to understand the development of the industry itself. It is proposed to confirm this theory with the help of experts.
2	Economic	**Common Russian market situation** Russia lags behind both in its own development, and in principle in the application of methods of analysis of	Now a good phase to start business in Russia in this area, the niche is not yet very busy and has all the

		the genome. Now, at the state level, there are all prerequisites for the development of this direction and obtaining funding for its own development.	prospects for financing. It is proposed to confirm this theory with the help of experts and secondary information.
3	Economic, Social	**Market volume and the trend of changes** According to the studies and forecasts, the following data were determined: Sequencers' potential on Russian market is no more than 1000 sequencers. The number of capillary sequencers is 85% of the total volume and is 200 000 - 300 000 analyzes per year (information of 2015). (Arustamova 2015, p.31.) There was information that all together 120 analyzers have been installed, of which only 20 are used regularly (Yashina, Malacho & Sorokoletov 2016, pp.182-186.). For 2015 the market of full genomic sequencing in Russia increases annually an average of 15% (Yashina & Malacho 2015, pp.49-55.). According to 2016 in the opinion of different experts, the increase in research in commercial laboratories and annual growth of the market is 20-30% (Rusbase).	On the base of secondary information and experts' interview an attempt will be made the volume forecast of the market on the basis of the trend indicated in the theory.

4	Political, Economic, Social	**Problem factors for development** The problem of registration and staff is one of the keys in the transfer of gene research from the research field to the medical.	On the basis of the theory, it was revealed that in addition to funding, the greatest impact on the development of the field of genetically modified medicine is influenced by the problem with high skills personnel and at the macro level - registration bottlenecks, which do not allow the transfer of the genome research into the medical field.
5	Economic, Social	Features of financing The development of the popularity of genetic tests will strongly influence the inclusion of them in the mandatory or voluntary insurance program. If this does not happen, then the development of the market will depend on the willingness of ordinary people to pay for these services from their budget. Also an important aspect is the territorial distribution of medical institutions, as by sources of financial resources, the richer regions have more prospects for the development of innovative directions.	Based on the empirical analysis, will be tried to predict the inclusion of these genetic services in the budgetary sphere on the basis of expert predictions. Also, it will be tried to find out whether the territory really influences the development of genetics. And also based on the survey of ordinary people, will be tried to build a forecast of people's willingness to pay for services independently, and try to find patterns.

5		Not reflected in theory - the company's ability to distribute a new product through an existing distribution set. This issue is not subject to theoretical justification, but is necessary for research only from an empirical point of view.	The Case company expects to interview representatives of its distributors in order to get an understanding of the possibility of using current customers for selling and promoting a new product.

Table 4. Theoretical statements

3 APPLYING QUALITATIVE METHODS IN ANALYZING PROSPECTS OF GENOME RESEARCH MARKET

This chapter presents the research approach and the methodology chosen for the study. The chapter continues by explaining the research phase and the methods used for collecting information and analyzing empirical data.

3.1 Comparison and choice of research methodology

Forecasting of demand of Genome Research on Russian market will have a quantitative estimate in quantity of tests, which can be made in this field and a quantitative evaluation of the sequencers that can be installed on the market. But in this study, it is more important not to exact the number, but trends, factors that will affect these indicators.

Qualitative research is aimed at obtaining profound, detailed information about the subject of research. Unlike quantitative methods, they focus not on statistical measurements, but rely on understanding, explanation and interpretation of empirical data and are the source of the formation of hypotheses and productive ideas. (Stanway 2016.)

Forecasting the number of Genome Research tests will have a rough estimate and without expert explanatory influences it will say anything to company - how this industry will develop, or is it possible for commercial company to take part in this business.

In a quantitative study, scientists tend to objectively move away from the topic. That is

why quantitative research is objective in approach in the sense that it seeks only precise measurements and analysis of target concepts for answering the question. For this thesis more interesting are deeper studies of the subject, factors, behavior of this direction and the reasons that underlie this behavior. (DeVault 2017.)

Qualitative research will allow capturing stereotypes that have not yet taken shape in the mass consciousness, to receive information at the time of its inception in the minds of individual consumers, which can later become mass (Crossman 2017). Qualitative and quantitative researches may use information about the same topic; qualitative methods rely on information that is not easily measurable while quantitative methods deal with data.

The collection of data for the research will contain two phases:

- Secondary data
- Primary data

3.2 Secondary data collection

The secondary data used in carrying out a so-called cabinet marketing research is understood as data collected earlier from internal and external sources for purposes other than marketing research purposes. In other words, secondary data are not the result of special marketing research. Such collection of information is the most affordable and cheapest method of conducting market research. For small and sometimes medium-sized organizations it is a mentally dominant method of obtaining marketing information. Internal sources include company reports, interviews with sales staff and other managers and employees, marketing information system, accounting and financial reports, etc. External sources are information from international organizations; laws, decrees; regulations of state bodies; speeches of state, political and public figures; data of official statistics, periodicals, the results of scientific researchers, etc. The existing information can be analyzed to generate new hypothesis or answer research questions. (Tripathy 2013, pp.1478–1479.) The collection of secondary information usually precedes the collection of primary information.

In the Table 5 is presented the structure of collection secondary information.

Type of sources	Name of sources	Comments
Internal sources	Companies' IT "Tender" system	Case company conducts analytical work on the control of publication of tenders in the health system and monitoring of the results of trades with notes in IT system for future analyzing.
Internal sources	Expert Reports of exhibition visits	The company cooperates with experts who visit local and international exhibitions and congresses and provide reviews of reports on the latest market trends including Genomic Medicine.
Internal sources	Analytics of the operation of equipment, quantity and type of research, costs in a cooperating laboratory in the direction of genome research	The company has a collaborating private laboratory, that is engaged in this direction of medicine and in which pre-treatment data can be obtained.
External sources	http://www.zakupki.gov.ru	The site on which all state tenders are carried out in the Russian Federation and information is available about the equipment supplied on the market of genomic medicine. (Zakupki)

External sources	https:// tenderplan.ru/	The paid platform for viewing and analyzing data about state trading in Russian Federation. (Tenderplan)
External sources	http://base.garant.ru/	Law regulation of Russian Federation, including Health care and Genomic Medicine. (Basegarant)
External sources	roszdravnadzor.ru	Web site of The Federal Service for Supervision in the Sphere of Social Development and Health (RosZdravNadzor). The site provides information about all registered medical products, as well as violations of the conditions for the circulation of medical products in the Russian market.

Table 5. (Structure of collecting) secondary data sources

Secondary data help the researcher to get more acquainted with the situation in the industry of Genome Research, the trends in the changes in sales and profit, competitors, the latest achievements in science and technology, and other. Secondary information will help proceed to the correct collection and investigation of information of primary data.

To determine the trends of the Russian market, it is good to consider the market from two sides:

- Commercial companies

- State institutions

These companies have different approaches to procurement and freedom in action. Unfortunately, the information of commercial companies is closed. Therefore, the main research will be carried out on the basis of state institutions - since information on their procurement can be accessed through the tenders.

Main theoretical statements which will need to be determined by analyzing secondary information are **common Russian market situation, market volume and the trend of changes and features of financing.**

Analogously to the mentioned study of Yashina et al. in 2015 and in 2016, an analysis was carried out of tenders of state purchases on the system tenderplan.ru, zakupki.gov and other related tender and registration (RosZdravNadzor) systems for last 4.5 years. The goal is to identify the supply of basic models of sequencers, consumables, type of purpose: science or clinical practice, and related services; and also identify the main players and brands on the market.

To check the information about delivered analyzers at this stage, the following analysis procedure was made: to check state trading on the sequencers and to reveal the confirmation of the theory about the number of installed analyzers, and main consumables.

Also in the theoretical information were data about the non-using of most of the installed equipment for different reasons. The reasons, why they could not be used, was planned to find out at the next stage of the study - during the primary data collection. In the analysis of secondary data, the author will try to find only confirmation or refutation of this theory.

The methodology will be the following – to check where the sequencers have been sold for the entire time; after to check if these buyers made publications on the reagents, raw materials and service in the period after they bought analyzer. As usual, all equipment, services and materials in Russia should be purchased by state institution through the central state trade system (tender or auction). If after buying the sequencers the institution did not buy any devices for them or services, then it is most likely that they are not used them.

Moreover, for this research the interest was in the purpose analyzers are used:

- clinical practice
- research activity

It will be able to find out this in the following way:

- To check all registered analyzers, related reagents and materials in the Roszdarnadzor;
- To select from the all tenders registered models and where the institution has a license for medical activities.

Based on the results of the study of secondary information in this research, it will be possible to compare them with the theoretical definitions of the market from the previous chapter and make a general conclusion about the coincidence or inconsistency with the indicated information by experts.

3.3 Primary data collection

Primary data is the initial information received for exact purpose. The main advantages of primary information: data are collected in strict accordance with the precise objectives of the research task; the methodology for data collection is strictly controlled. The process of collecting information will involve the generation of large amounts of data and can use different collection method (e.g., focus group, one-to-one interview and other). In addition there are also different ways of making a record of what is said and done during an interview or focus group, such as taking handwritten notes or audio, video-recording. (Sutton & Austin 2015. pp.226–231.)

The feature of data collection in this study will be the separation of target respondents. Based on information will be prepared interviewees of practical persons to get their opinions from expert side. Interviewing as research method is useful for collecting data that reveal the values, perspectives, experiences and world views of the population under study, and is often paired with other research method (Crossman 2017). It is planned to make an overview of existing technologies with the display value of genome tests based on local market conditions and international situation. In this research there will be made three types of questionnaire for different groups. In Table 6 there is information on the segmentation of respondents groups for obtaining information and the main tasks for this research.

Respondents group	Group members	The main purpose of communication with them	Planned way of collecting information
Experts	Medical or scientific personnel - final users, who understand what would make their working life better, trends in genomic medicine and its practical application.	The goal is to get an expert assessment of the market and the factors that influence the development trends; to determine the current situation and the number of tests and growth (fall) trend.	Semi-standardized interview in personal conversation or by phone.
Sales staff	Representatives of the companies who are now distributors of Case company in Russian regions and are engaged in sales of laboratory products in medical institutes.	To identify the trends of genetic medicine in separate regions and the readiness of the present distribution network to promote a new product in Genetic area.	Semi-standardized interview in personal conversation or by phone.
General public	People of different social groups	To identify what general public know and their readiness for genetic research	Electronic survey

Table 6. Segmentation of respondent groups for information collection

3.3.1 Experts' interview

To get an overview of the situation on the market, discussions are planned with specialists who are involved in the process of laboratory diagnosis and in particular of genetic studies. Interviewing was planned to make in semi-structured type for rod topics for discussion, allowing respondent to develop ideas and interviewer uses prompt to probe and keep up the conversation covering the broad areas. Interviewer may contribute but mainly one-way information flow. (Harrell & Bradley 2009.)

The specific preparation of the interview involves making decisions on a number of key research questions. Such questions include:

- the choice of respondents,
- drafting a questionnaire,
- determining the time and place of the interview,
- determining the recording method. (Belanovsky 2001, p. 49.)

a. Choice of respondents

The number of respondents in the study is usually determined by its goals, as well as the financial and time capabilities of the researcher. The presence of financial constraints often causes the researcher to reduce the number of interviews to a minimum, which should increase the accuracy of their "sight." In the case of genomic medicine research, restrictions are also due to the fact that this area is closed and experts generally do not want to contact.

In case that the totality of the surveyed respondents is considered to be homogeneous, the most appropriate number of respondents is about 20 people. This figure is determined from the practical experience of various researchers. As an example, the French sociologist Alain de Vulpion, specializing in the method of in-depth interviews, reported at a seminar in the Russian Academy of Sciences in the early 1990s that during the surveys he initially interviewed 50 people, but then he became convinced that 20 people was enough. (Belanovsky 2001, p. 50.)

The mentioned number of respondents is sufficient to form a typological picture based on their answers, although it is inaccurate from the quantitative point of view, which,

depending on the purposes of the research, can become either its final result or a starting point for further work.

The author of this research will seek to interview 20 experts who must meet the following requirements:

- Have medical or biological education;
- Have practical experience in the laboratory or genetic researches area (including PCR).

When selecting respondents, the author should also ensure that the composition corresponds to the following at the place of work; purpose of genetic research (clinical practice or research activity), and work in commercial activities or in a state institution. It is important that representatives of all groups are included in the selected experts for the interview.

As it was described in the factors affecting the economy in Russia, it is a very important region of respondents. Initially, Moscow and St. Petersburg are more developed and "rich" regions in comparison with other cities. Therefore, it is important that in the selected respondents were representatives of at least three groups:

- Moscow, St. Petersburg;
- Big cities, population more than 100 000;
- Small towns of regional subordination.

It is also important that the activities of commercial companies and laboratories are very different from government institutions, primarily because of sources of funding and freedom in the choice of direction of activities. Thus, it is necessary to reflect the opinion of both groups.

b. Drafting a questionnaire

Questionnaire was developed with taking into account the main research question and sub questions which were noted for this research. The main aim was to understand an expert assessment of the current market and the factors that influence the development trends and how they will influence the demand of genome research tests.

Interview was a semi-structured type and suggested that some topics could be more widely covered in terms of experience and expert's opinions.

Drawing of basic topics and questions are indicated in the Table 7 with some comments from researcher. But in fact, in a semi-structured interview, questions can be exchanged in places or even missed. In the mentioned form are the basic questions that the interviewer needs keep in mind.

Reg. №	Name of respondents: Specialization: Education:	Region (city): Place of work: Area: clinical practice / research activity	Date of interview: Place: Interviewer:
№	**Topic/question**		
1	What is your experience in genome research tests?		
2	How do you evaluate developments on the world market? What are the basic manufactures you would advise?		
3	What do you think about Russian developments?		
4	What do you think is the future of this direction?		
5	Is it necessary to use the genome research in medicine? What tests would be popular in your opinion?		
6	Is it necessary to include the genome sequencing of the genome in a mandatory diagnostic program?		
7	How can we determine the volume of the equipment market and the market for research?		
8	Do you think people are ready to pay for this service themselves?		

Table 7. Questionnaire (structure form) of experts' group

c. Determining the time and place of the interview

Representatives of the group are quite scattered and each had to choose the right approach and way for the interview.

The Case Company cooperates with several experts in the framework of its actions – these experts were interviewed in a personal conversation in the office of the company or at the direct place of their work (in the lab or place of production) in the period from 01 August to 31 August 2017.

Another part of the experts was interviewed in October on the exhibition "Laboratory City – 2017". Eleventh-thirteenth October 2017 The Federation of Laboratory Medicine held the III Russian Congress of Laboratory Medicine, which brought together

laboratory specialists from all regions of Russia on its site. Within the framework of this congress, there are many specialized lectures, including some on the direction of genomic technologies and molecular diagnostics. In addition to an extensive program of scientific and practical events, there was exhibition "Laboratory City", where major players of laboratory market had their own booths and presented laboratory equipment, reagents, consumables and some new technologies.

Case Company also had a booth in this exhibition and the researcher used the chance to communicate with experts to identify the issues of this survey.

After summing up the results, the researcher checked whether all the requirements for the choice of the respondents were satisfied and whether the number of interviews was sufficient. The missing 5 interviews were conducted by phone - they were representatives of small towns in the regions.

d. Determining the recording method

Methods for recording interviews for documentation and subsequent analysis include audio typing, video recording, handwriting and memorization. Today, a dictaphone is usually used for this. In this case, the interviewer can focus on the topic of the interview and the dynamics of interaction. The words, the tone to which they are pronounced, pauses and the like are imprinted forever, and then you can return to them again and again. (Polgar & Thomas 2011, p.110.)

The author originally planned to record at least a few interviews to provide the management with the audition and justification why some conclusions were made in this way. But during first interviews it was revealed either that the respondents refused to admit that this sphere has not been thoroughly studied yet and they would not want their words "to go somewhere" and ruin their reputation. Or they were constrained and could not say something freely until the recorder was turned off.

On the basis of the above, it was decided to use the method of written records with the author's notes.

3.3.2 Sales staff interview

One of sub-questions of this research was to understand the ability for Case Company to promote new products in Genetic area through an existing network of distributors and also to identify the trends of genetic medicine in separate regions.

Case Company worked directly with final users (state hospitals of private clinics and laboratories) in Saint-Petersburg, where the head office is situated, and in Moscow, where a branch of the company is situated. In all other regions company works through a distributor net and through local companies. For this step of research Case Company decided to make survey of these clients to understand what they know about the area of gene medicine and their opinions about the future of this direction.

The information was also received in the form of a semi-structured interview with the possibility of expanding the answers.

a. Choice of respondents

Formulation of respondent list was prepared and confirmed two times.

- "First list". One main distributor in each region was selected, where company has active promotion. In total there were around 30 companies, which now re-sale Case company's products and have strong positions in regions in this field. 26 agreed to cross the interview, others cancelled.

- "Second list". A new selection of companies was made – clients of Case Company, who are involved in genetic medicine more.

b. Questionnaire for sales staff

The questionnaire for sales personnel differed from the questionnaire for experts and was developed specifically taking into account factors related to sales process and presented in the Table 8 with some comments from researcher.

Reg. №	Name of respondents: Specialization: Education:	Region (city): Place of work: Area: clinical practice / research activity	Date of interview: Place: Interviewer:
№	**Question**		
1	What is the main direction of your company's activity (main products)?		
2	Do you have any experience in supplying molecular diagnostics?		
3	Do you cooperate with the research institutions?		
4	Are you familiar with the topic of genome sequencing and related equipment?		
5	If the company promotes this equipment, have you got opportunity to implement it in your region?		
6	Do you think there is a prospect for this direction if the cost of the test is USD 3000 and it is not included in the budget programs?		
7	Is there any regional support for the direction of genetic tests?		

Table 8. Questionnaire (structure form) of sales staff respondents

c. Determination of the time and place of the interview

The interview of "First list" was conducted between 01 August to 20 August 2017 with the assistance of an internal call center specialist. The interviews were made by phone or skype.

After the preliminary conclusion of results a decision was made to make a second selection of respondents. Additional representatives of companies from the "Second list" were interviewed from 09 October to 16 October 2017, also by phone personally by researcher.

d. Determining the recording method

Unfortunately, the Case Company recently experienced an unpleasant experience with recording calls, so recording calls is not working now. In the beginning of 2017 when a special internal call-center specialist was taken to the staff, the technology of recording calls with the interlocutor's notification of the recording was experimentally introduced. Afterwards it was possible to listen and analyze not only calls by the mentioned specialist, but also by all employees, including sales managers.

But the company's customers began to complain massively and began to call to manager's mobile phones or use correspondence like mail or messengers. In the company's conversations with third parties there is no any secret or illegal information,

but customers complained that they felt they were under surveillance.

It was decided to cancel this tactic, so for the phone interview audio recording was not available. Therefore, despite the advantages of audio recording of the interviews, the researcher used the method of manual recordings during conversation.

3.3.3 General public survey

The purpose of talking with people was to identify what ordinary people know about the area of genetic medicine and their readiness for such tests. And on the basis of their opinion to forecast how this area can evolve in the future in terms of final consumers. The market of medicine is certainly specific - products on the market are not always chosen by users - as a rule they are "imposed" by their medical institutions or certain standards. But in any case, the trends of personalized medicine go forward and the imposition of ordinary patients will also be important.

a. Choice of respondents

For the selection of ordinary people for the survey, some of the same rules applied as for the survey of experts, like geographical position. But also new requirements were added:

- In the survey had to participate people of different social groups;
- People should have no medical or biological backgrounds.

For the survey, it was decided to obtain data from at least 40 people. But after the completion of the survey of 26 people it was found out that there were not enough people from the regions (Most from Saint-Petersburg, because researcher distributed information about the survey through their friends) and the invitation about the survey was sent to the regions and 16 more answers were collected. As a result, the survey involved 42 respondents.

b. Questionnaire

The survey was conducted in electronic form without contacting the participant directly. It was made in Russian language and contained not only the users' forecasts about gene medicine, but also some personal questions for determining their social group, preferences and habits. Questionnaire consists of following topics and questions,

presented in Table 9.

№	Question	Answer options
1	Age	Number
2	Place of residence (city)	Selection
3	Position/specialization	Selection
4	Average monthly income level	High Middle Low
5	Are you familiar with the concept of sequencing of the genome?	Yes/No
6	Are you ready to pay $ 3,000 to fully decrypt your genome and know about all the predispositions?	Yes/No
7	If not, how much do you think should such a test cost in USD?	Number
8	If there is a possibility of not full research but only parts of the genome associated with a certain area (eg predisposition to breast cancer, or mutation gene), it would be interesting	Yes/ No /Depend from price
9	Which areas are most interesting?	Oncology/ chronic diseases (heart, blood vessels and others)/ Mutations/Related genetic features/ Other
10	Would you prefer to do such a test in a private clinic or state?	Private/State

Table 9. Questionnaire (structure form) of survey of general public respondents.

c. Time and place

When conducting an electronic survey, the time and place of the interview is not so important, since respondents have the opportunity to reply at any convenient time, regardless of their location. On-line survey with using Google tools was conducted from 2 to 24 October 2017. In Figure 5 is shown the title page of the Survey.

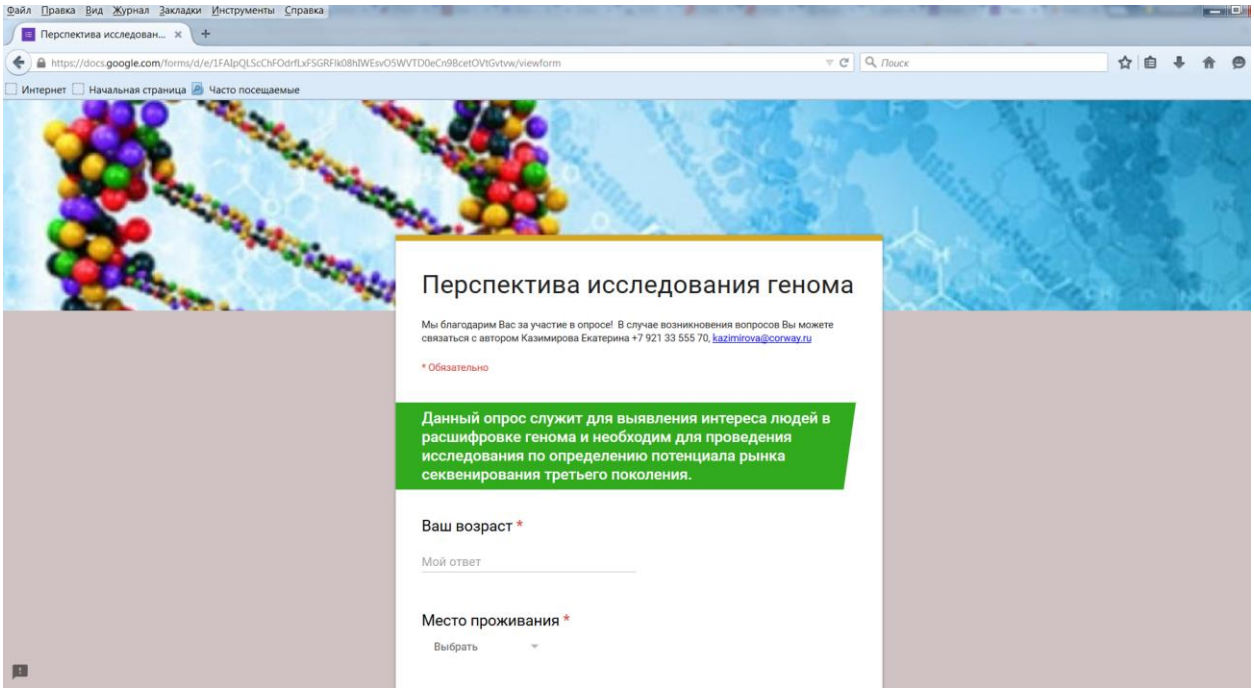


Figure 5. Main page of on-line survey

d. Recording method

Google tools can give the data in a convenient electronic format. Data was uploaded for analysis to Excel for later analysis. The results of the report are listed in the appendix 3.

3.4 Methods of analysis

Since the research was make in two main stages: analysis of secondary data and analysis of primary data, several approaches to analysis were used.

3.4.1 Secondary data analysis

During research of secondary data from internal and external sources were used two general approaches for analyzing existing data:

- the ‘research question-driven’ approach;
- the ‘data-driven’ approach.

In the research-driven question approach, there is a priori hypothesis and then researcher looks for suitable datasets to find answers on the question. In the data-driven approach the researcher glances through variables in the available information

sources and decides what kind of questions can be answered by the available data. In reality, the two approaches are often used jointly and iteratively. (Cheng & Phillis 2014, pp. 371–375.)

In the analysis the researcher start with a general idea about the question or hypothesis and then looks for available datasets which contain the variables needed to address the research questions of interest. Main theoretical questions which will require secondary information are:

- Common Russian market situation,
- Market volume and the trend of changes,
- Features of financing.

3.4.2 Qualitative Content analysis

For analyzing data from Expert and Sales companies' respondent groups for primary information analyzes it will be possible to find regularity and common opinion. Qualitative Content Analysis method was used which defines itself within this framework as an approach of empirical, methodological controlled analysis of texts within their context of communication, following content analytical rules and step by step models (Mayring 2010, pp. 43-55).

Presentation of findings will be presented in tables and matrices. This way is useful particularly when quotations are used to articulate the findings by interview. Refinement of the analysis may well occur even as the manuscript is still being written in final form (DeVault 2016).

In the procedure of content analysis was made the selection of semantic units that are directly relevant to the problem under research question. In the theoretical part was fixed a number of theories that related to the research questions and questions which should be opened more detailed in the empirical part. These theories relate to the following topics:

- International market development
- Common Russian market situation

- Market volume and the trend of changes
- Problem factors for development
- Features of financing
- Current distribution set of Case company

Since the interviews were conducted in semi-structured form, much of the information received from experts and sales representatives was logged not in the form of an organized completed questionnaire, but in the form of a written text, to the author's digressions and sometimes respondents leaving the topic or on the contrary of deeper development of one topic, while not having concepts about something.

The next stage was one of the most important in the whole process of content analysis. This is the codification of text units. Its essence is to develop rules for correlating semantic units with a list of categories of analysis. The result of the codification phase is the development of a codifier, which includes not only a list of observed indicators, but also data on the document in which they are present (Flick 2009, p. 334).

After forming a sample of messages, selecting semantic units and creating a codifier, researcher went directly to the very analysis of the texts of interviews. In practice, this is expressed in the compilation of a code table in which each observation (the semantic unit) refers to a particular type or class in accordance with the rules of the codifier. In Table 10 are presented the basic codes that were developed and used by the author for comparing information and searching for the answers to the questions asked is discussed.

Basic Codes	Theoretical statement/ open research question
USA, Illumina, Roche, Thermo fisher, Oxford Nanopore, Bio-rad, China, Beijing	International market development
Skolkovo, Nanofor, market frozen, Russian research center (RRC), test cost, high test cost, non-use.	Common Russian market situation
Market of equipment, market of tests, market growth,	Market volume and the trend of

import substitution, tender, Medicine usage	changes
Registration, staff, bioinformatics, budget support.	Problem factors for development
Medical program, insurance, mandatory diagnostics, budget	Features of financing – state politic
Solvency, ability to pay, insolvency, inability to pay, test cost	Features of financing – individual readiness for pay

Table 10. Codifier table

3.4.3 Statistical Survey Analysis

For the analysis of surveys of ordinary people, the Content Analysis with special coding is not required – interview form in electronic form is a closed one, aimed at obtaining statistical data and searching for patterns. This Statistical Analysis needs to find answer on one of research sub-questions – "Knowledge, expectations and readiness of ordinary people for the topic of genome research". For this study, it is interesting to understand if the state policy of financing in the field of genetic medicine is not being implemented in the next few years, and whether the society is ready to incur expenses on its own.

Statistical Analysis was made on the basis of survey and used the most straightforward form of analysis, and one that often supplies much of the basic information need. It was planned to tabulate results, question by question, and it was done using an original questionnaire and writing on it the frequency or number of people who 'point each box'.

Relative values in statistics are generalizing indicators that reveal the numerical form of the ratio of two matched statistical variables. In the calculation of relative values, two absolute ones are most often compared, but one can compare both the mean and relative values, obtaining new relative indices. The simplest example of calculating the relative value is the answer to the question: How many times is one number greater than the other. (Callegaro, Vehovar & Manfeda 2015, pp. 187-191.)

Qualitative data from survey needs to be evaluated as available information and data are increasing permanently in modern times. There are some difficult methodic

approaches for consistently transforming qualitative contents into a quantitative form and enabling the appliance of formal statistical methodology to get interpretations and insights which can be used for sound decisions and which are bridging qualitative and quantitative concepts combined with analysis capability. (Loehnert 2010.)

But this survey research does not require such detailed elaboration of mathematical concepts and statistic correlations and will be reduced to an estimation of relative indicators - like "how many people are ready to pay for carrying out gene research, how much they are ready to pay" and a small search for regularities - for example, regional affiliation or age. Qualitative answers, if possible, will be transferred to a quantitative assessment, or if conditions are encountered, codes or interesting information will be reflected in the conclusions as an addition.

4 EMPIRICAL ANALYSIS OF THE GENOME RESEARCH MARKET

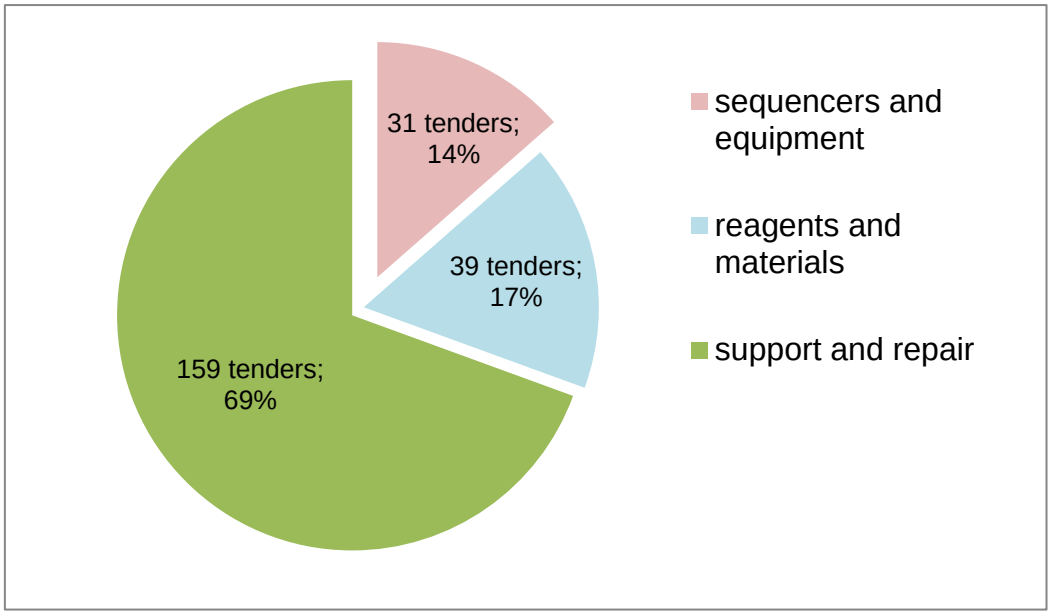
4.1 Analysis of the market and trends through tenders and registration system

Analogously to the mentioned research of Yashina et al. in 2016, an analysis was carried out of tenders of state purchases on the system tenderplan.ru and related systems mainly for last years since 01.01.2012 till 31.08.2017. The goal was to identify the supply of basic models of sequencers, consumables and related services. And also to identify the main players and brands on the market.

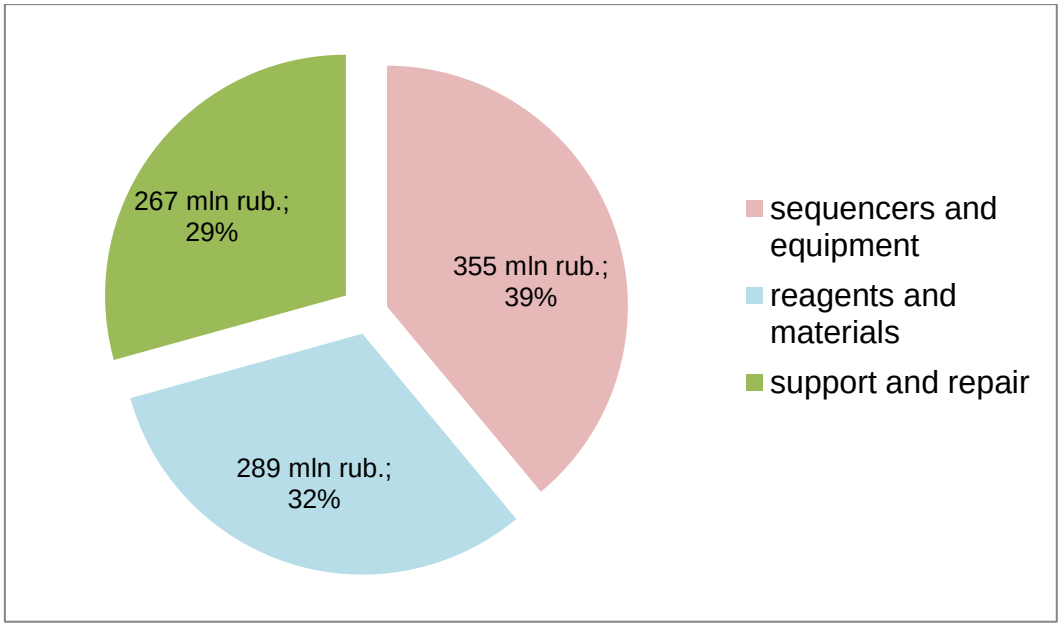
In addition, there was a number of narrower tasks, connected with theoretical background and related to common Russian market situation, market volume and the trend of changes and features of financing.

Determining the main characteristics of the market

In the period from 01.01.2012 to 31.08.2017 were found 226 tenders for sequencers, raw material for them, or service for the total 911.2 million rubles of contracts. Of these, 31 tenders were for the supply of the sequencer and the amount of contracts was 669.8 million rubles. The Graph 1 shows the percentage distribution of the objectives of the tenders by quantity and Graph 2 by sum of contracts.



Graph 1. Share of quantity of state tenders in the field of sequencing by object of procurement from 01.01.2012 to 31.08.2017



Graph 2. Share of sum of contracts of state tenders in the field of sequencing by object of procurement from 01.01.2012 to 31.08.2017

Data on the results of tenders do not give us a clear view about theoretical statements of market volume on current day, because:

Firstly, only state trades were checked, and there was no possibility to check current situation on commercial market.

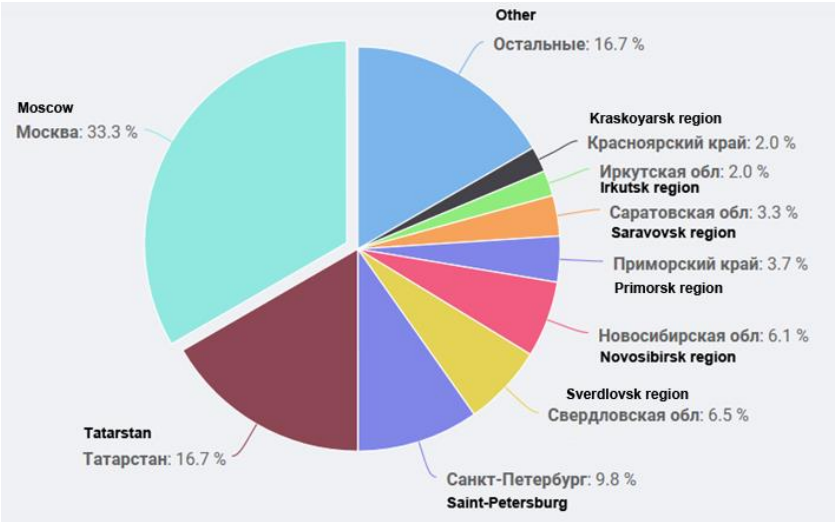
Secondly, in the process of analyzing tenders, it was revealed that state institutions purchase materials or repairs, but there were no noticed tenders for the sequencer itself. This could mean that sequencer was placed there without a tender.

In the Appendix 1 the Case Company can find a list of distributors that currently operate in the market for the supply of sequencers and materials to them and most often (more than 6 participation in tenders) participate in public procurement. This information gives us an understanding of the competition in the genomic research market.

According to the theory on the Russian market in 2015, more than 85% are occupied by sequencers of the capillary type (the old generation). In fact, in the analysis of trades, the models that mainly participated mostly belonged to a new generation sequencers. In principle, this can neither subjoin the theory nor disprove it, because if the institutions were supplied with old type analyzers and they are not used, then it will not see trades for materials to them either.

Geographical location

The distribution by region was carried out by analyzing the location of the buyer's actions in the tenders trading by sequencers and noted in Graph 3.



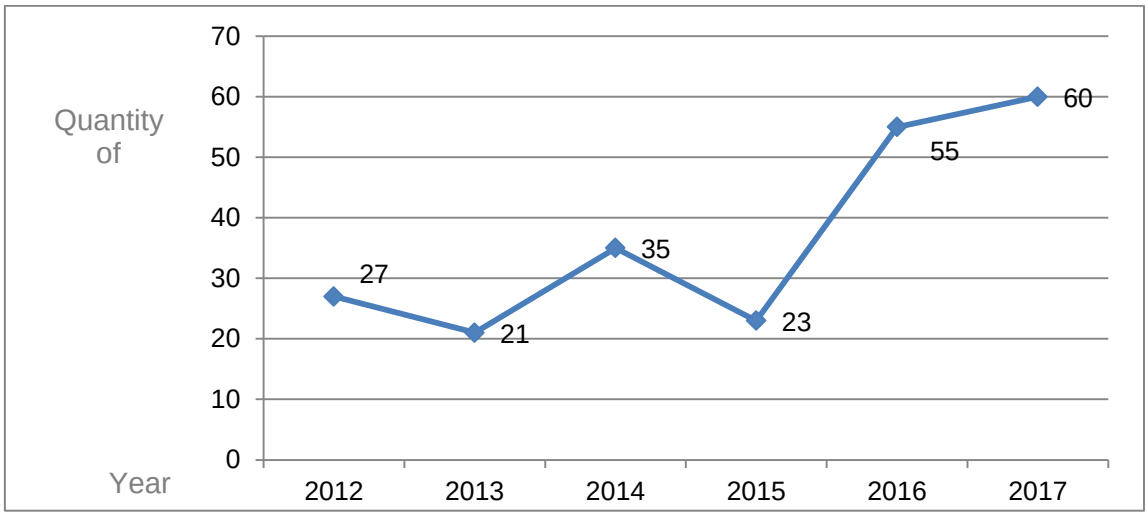
Graph 3. Distribution of state trading on a regional basis

This analysis underpins theoretical statements that there is larger financing of medicine in the regions that are tax donors.

Trend

According to theoretical estimates by experts, in 2015 and 2016 the forecasts were as follows: 15% market growth as a whole, 20-30 % market growth annually in the commercial sphere.

During analyzing tenders, it was revealed that the growth trend had greatly increased in the last two years and if in 2015 there were only 23 tenders on this subject, then in 2016 there were 55, which is a growth of more than 100%. The dynamics of the competitions held in the direction of the sequencers is indicated in the graph 4.



Graph 4. Development of the area of genetic research on the basis of the number of published trades in years 2012-2017.

Determination of usage type

In theory, it was pointed out that most of the sequencers are used for research purposes and are not yet advancing to the medical field. According to web site RosZdravNadzor in Russian Federation now only 7 models of sequencers have registration certificate, 2 of which have already expired registration date. Models are mentioned in Table 11.

Number of registration	Date of issue	Expire date	Name of model	Company, who made registration, Country	Manufacture, Country
МЗ РФ № 2001/444	08.05.2001	08.05.2011	DNA Analyzer Automatic (Sequencer) Model "ALFexpress II"	Amersham Pharmacia Biotech Export GmbH, Germany	Amersham Pharmacia Biotech AB, Germany
МЗ РФ № 2002/646	14.08.2002	14.08.2012	DNA Analyzer Automatic (Sequencer) ALFexpress II	Amersham Biosciences AB Sweden	Amersham Biosciences AB Sweden
РЗН 2014/1568	29.04.2014	Indefinitely	Genetic sequencer MiSeq in the following versions: MiSeq, MiSeqDx	ООО "ИнтерЛабСервис" Russia	Illumina, Inc, USA
ФСЗ 2012/12198	30.07.2012	Indefinitely	Sequencer genomic "GS Junior" with accessories	ООО "Рош Диагностика Рус" Russia	Roche Diagnostics GmbH, Germany
ФСЗ 2012/13397	21.12.2012	Indefinitely	Sets of reagents and supplies for the sequencer genomic GS Junior	ООО "Рош Диагностика Рус" Russia	Roche Diagnostics GmbH, Germany
ФСЗ 2012/13293	29.11.2012	Indefinitely	Sequencer genomic GS FLX + with accessories	ООО "Рош Диагностика Рус" Russia	Roche Diagnostics GmbH, Germany
ФСЗ 2009/05210	04.06.2010	Indefinitely	The system for DNA sequencing (OpenGene DNA	ООО "Компания Медсервис"	Siemens Healthcare Diagnostics,

			Sequencing System) Trugene with accessories and consumables	Russia	USA

Table 11. The list or registered analyzers in RosZdravNadzor

Thus, only 4 models can be used for clinical research and use in medicine:

- MiSeq, MiSeqDx
- GS Junior
- GS FLX
- OpenGene DNA

Other sequencer presented on the market can be used only for scientific research.

To determine the model of the delivered sequencers, the researcher had to go into each contract and check the conformity of the registered brand and model from the contract, and also to check the application scope of the buyer (medicine or research). Of the 31 tenders, only 3 procurements were identified as for clinical aim, the remaining sequencers, even if they were delivered to medical institutions, should be used for research purposes and not the basis for setting the diagnosis for example.

The level of use of sequencers

According to the articles at the moment, about 120 sequencers by 2016 have been delivered, but only 20 of them are actually used (17%). The author mentioned all the sequencers delivered to both state and commercial companies. This study will only concern state trades because of the lack of opportunity to analyze commercial companies. With the help of the system of tenders, an investigation was carried out that supported this theory.

Based on the analysis it was revealed that out of 92 state customers only 46 during this period made a one-time purchase, which is 50 percent. The remaining 46 made purchases 2 or more times. But in the opinion of the researcher, this conclusion cannot

serve as a refutation of the theory, since the analysis of the tenders for selected period does not give a complete picture of the delivered analyzers, bypassing trades for research and approbation ways, for example.

4.2 Analysis of primary information

With the using of mentioned methods of analysis, the collected primary information was analyzed in the form of an interview, and the following results were found.

4.2.1 Summary and results of experts' interview

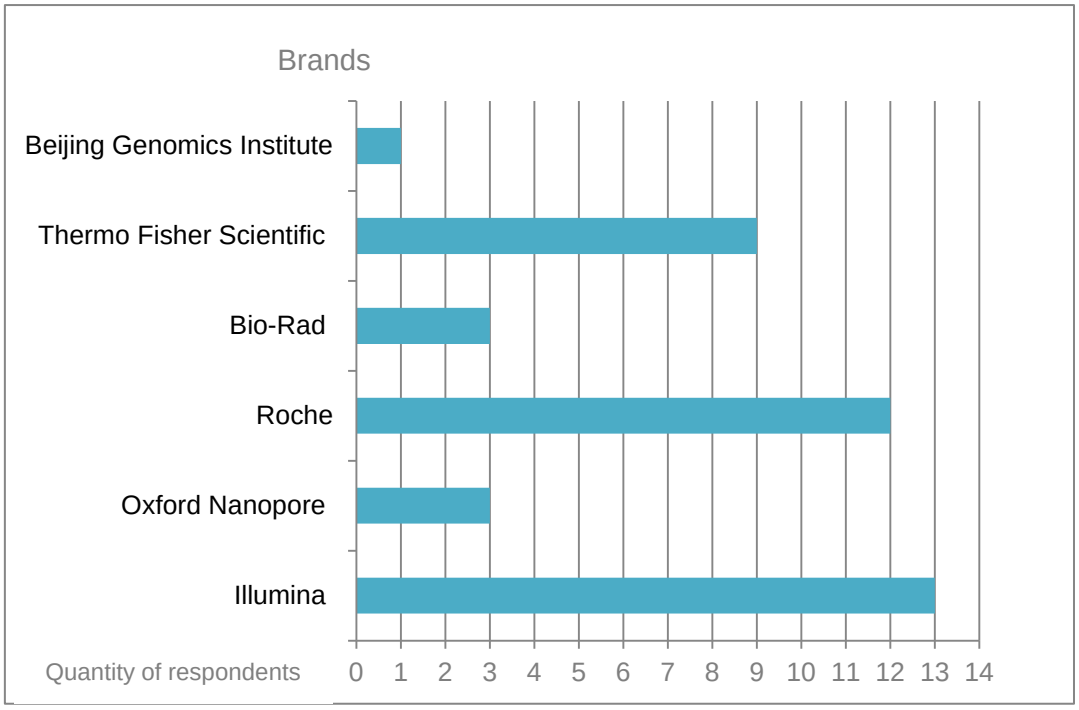
Interviews with experts include respondents from different areas for the most complete representation of the object of research and search for answers to questions. Appendix 2 contains translated interview protocol with one of the respondents, as an example of filling out.

Based on the results of the encoding of the data, including the theoretical statements, the following results were concluded.

International market development

Of the 20 respondents, most demonstrate interest and perspective in the development of genomic technologies and their application in medicine. There are also few scientists who think that DNA sequencing will not leave the walls of research laboratories. Two respondents suggested that these technologies are too scientific and expensive to be applied to mass analyses.

Graph 5 shows the number of known world brands based on the views of the respondents.



Graph 5 Familiarization of experts with world brands

The rest of the respondents, especially those who are involved in molecular diagnostics more deeply and take part in international conferences, state that there is a future for genetic tests. All interviewed respondents marked the same brands, known on the international market and were very skeptical about Russian developments in this area.

Common Russian market situation

The survey involved only three people who are directly related to the work of sequencers, the rest do not have such opportunity but most specialize in molecular diagnostics and are associated with this direction.

Experts assess the overall situation on the Russian market as "lagging behind", "lull", "poverty". The declared Russian developments are noted by most experts as obsolete, and the use of capillary sequencers (Sanger method) is not predicted due to the high cost of genome research.

According to the opinion of experts, the market of research is now mainly for scientific research and the market are waiting for the government to take steps in the transition of the genome research to the medical sphere.

Market volume and trend of changes

The main consumer of sequencers is now the scientific research center, which uses genomic research for the most part for population tests and genetic predispositions to diseases go only at the third level, after the identification of family ties.

Many experts (15 from 20) noted the growth of commercial influence in recent times and said that now these genome tests have become available in private laboratories and are in demand among wealthy people. But the problem is that human genetics is changeable and the results of such test can become outdated after a couple of years under the influence of external factors like the environment or internal, like food or bad habits.

If genomic researches pass to the medical level due to the state program then 8 experts noted that this would go into the routine of compulsory diagnostics. In this case, the equipment will have to stand at least in the Central District Hospitals. This assumption allows us to calculate the volume of the market for sequencers and tests for the projected inclusion in the compulsory insurance program.

Problem factors for development

The overwhelming majority of experts spoke about the issue of registration for making tests on the genome for medicine aim. Respondents noted that 1-2 years of registration deadline can stop the development process, since this area is quite variable and the reagents that undergo the registration process may be already outdated.

Also, the question that was not much raised as a problem in this thesis was noted by the majority of respondents - the availability of specialized staff for interpreting and issuing results.

Also, the problem for the development of the field of genome research is the cost of research. Now full genome code interpretation costs 2000 - 3000 dollars, a narrow, directed to some area about 300 - 500 dollars. What makes the test so expensive? In Table 12 are presented the results of the experts' opinion.

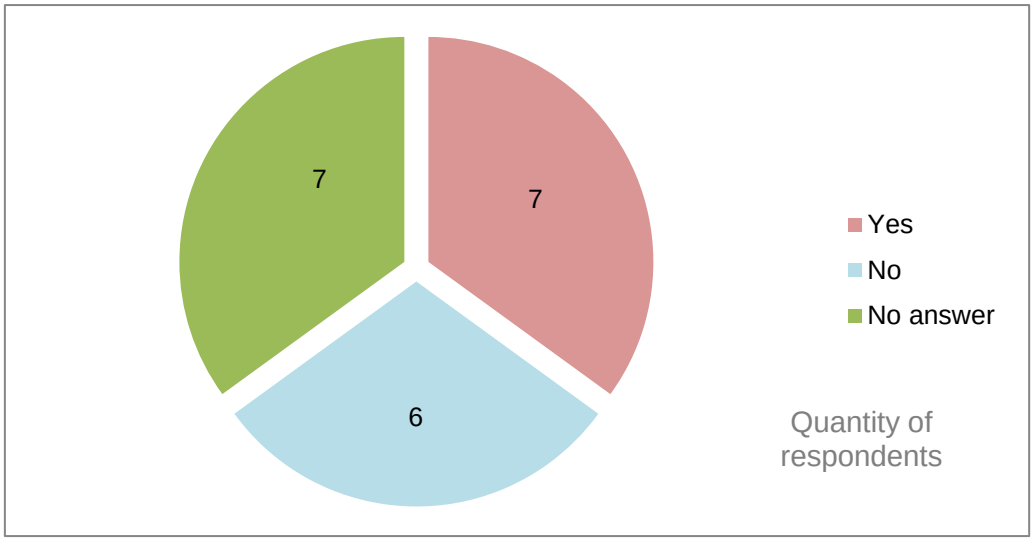
The constituents that affect the cost of the test	Level of influence (1 – strongest, 6 – weak)
Costs for specialized staff	1
Expensive technique	2
Overpriced market prices	3
Cost of equipment	4
Reagents	5
Maintenance costs	6

Table 12. Factors affecting the cost of the test

Also, 9 experts raised the topic of storage and legal responsibility of data. This topic was not considered at all in this thesis, and not learned during theoretical background. According to the respondents, this topic is not very well developed in the Russian Federation from legal side and can be a problem because it prepossesses storing or transmitting information about a person – full information about his predispositions, illnesses of features. As one of the experts said *"If the database with genome information is stolen and distributed, would you marry a person who has a mutation in the genome or a propensity for alcoholism? Or if the employer wants to check the employees… how to be with ethical point of view".*

Features of financing

According to theoretical notes, the main breakthrough in the development of the market will be if these tests are included in the program of mandatory or at least voluntary insurance program. The opinions of experts were divided according to the forecasts of this issue and presented in Graph 6.



Graph 6. Expert opinion on the need to include genomic research in the insurance program

Respondents, who answered “YES”, also commented on the following:

- *“When the test will cost $ 100”*
- *“When there are local products and the government will have to support them”*
- *“In mandatory unlikely, but in the premium voluntary will be cartainly”*

Respondents, who answered “NO”, also commented on the following:

- *“There are cheaper methods like PCR and ELISA, why need to use something more”*
- *“This science is far from practical”*
- *“It will be impossible to equip all hospitals with devices”*
- *“No staff in the country, they will learn at best in 10 years”*

At the same time, experts assess the high probability of popularization of these tests among the population and the development of this area in terms of personal payments of patients. Most experts believe that people would already be ready to pay, but they simply do not know about this possibility.

All respondents noted that the use of sequencers is primarily interesting in the diagnosis

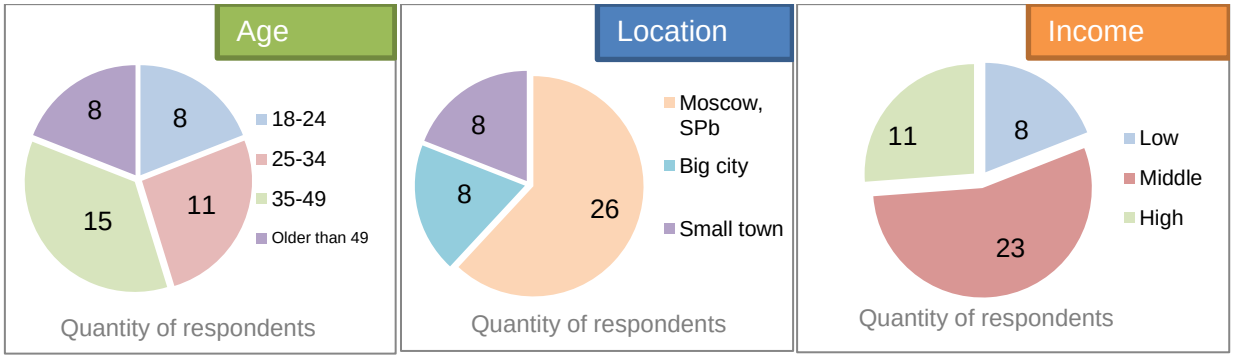
of cancer, prenatal medicine, diagnosis of autoimmune diseases and gene mutations.

4.2.2 Summary and results of general public survey

The idea of researching what common people think about the genome exploring appeared after studying the theory and communicating with some experts that many people would be ready to pay for deciphering their genome and without special budget programs. The result of this analysis gave an answer to the research sub-question – “Knowledge, expectations and readiness of ordinary people for genome research”.

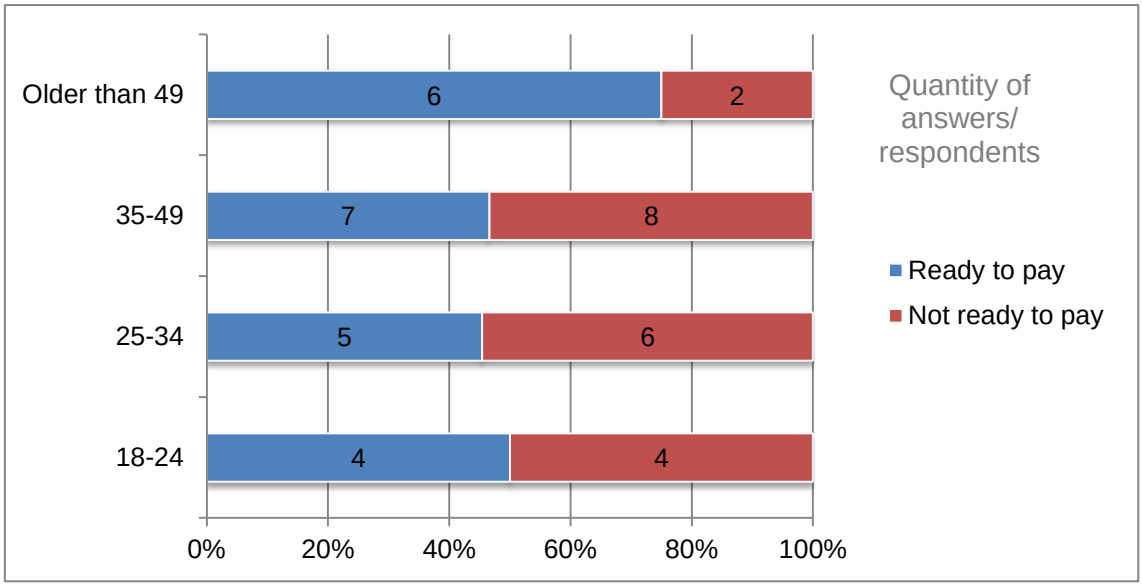
In the electronic survey took part 42 anonymous people. In the study were not accepted people with medical or biological background, since the goal was to determine what people think and if they are ready for such tests or not. In Appendix 3, the translation of the survey report with details of the data is indicated; this chapter will reflect the main identified patterns.

The author tried to reflect all the groups according to: location, age and income levels. The target groups are shown in Graph 8.



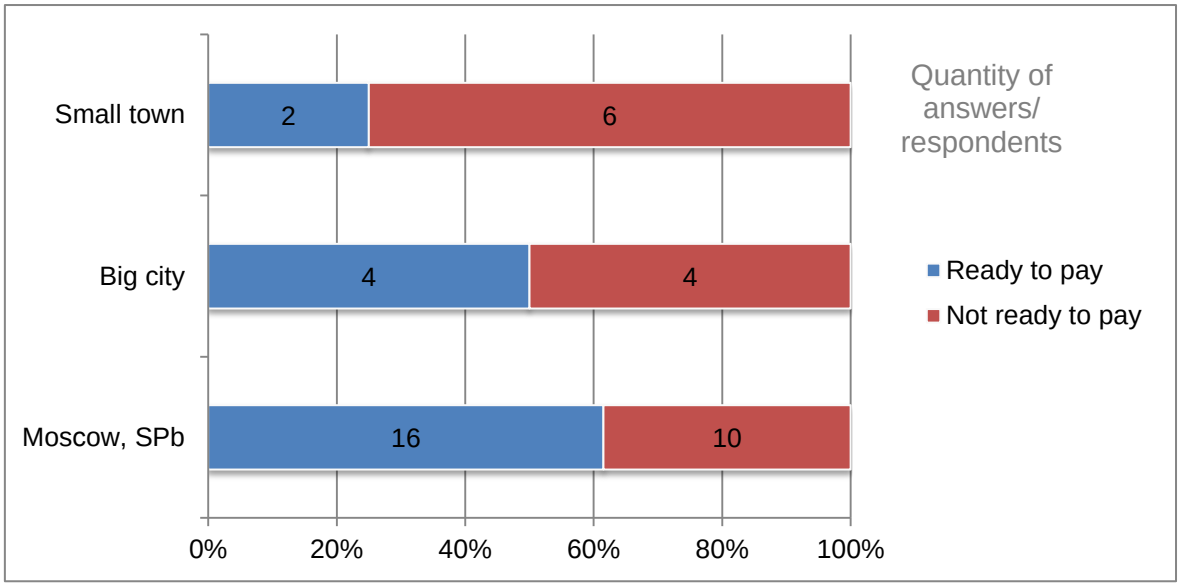
Graph 7. The structure of the survey respondents by age, location, income

A survey of people showed that people not related to medicine or science have not a lot of information about the possibilities of genome research – only 5 respondents have some knowledge about genome tests. At the same time, people's willingness to pay around of USD 3000 per one full genome research splits in half – 22 respondents are ready, 20 are not ready. Dependence on income, age and income is shown in Graphs 9, 10 and 11.



Graph 8. The willingness of people to pay for the genome research, the age dependence.

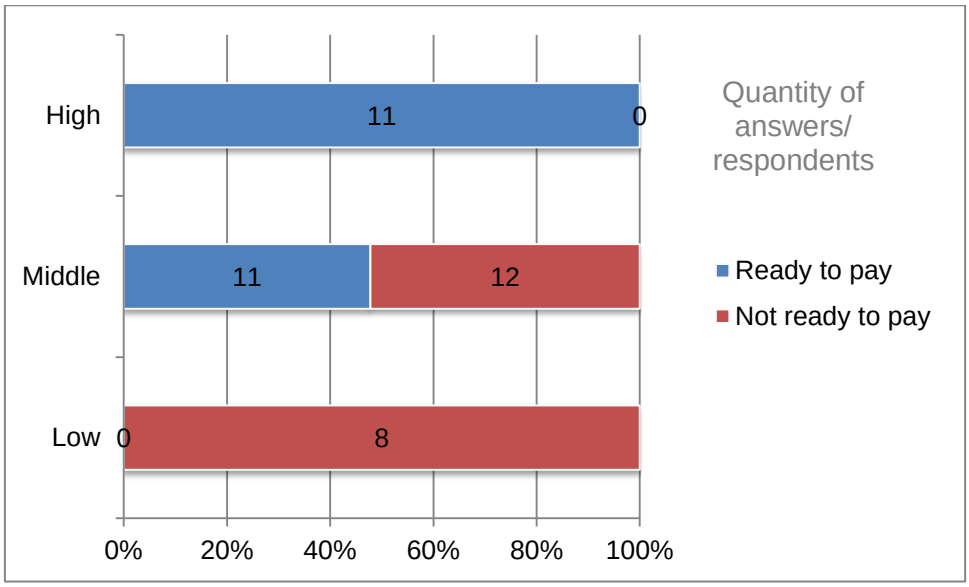
The logical conclusion is that the older people become the more likely customers as they are willing to spend money on their health and all sorts of tests. An interesting conclusion is that in the age group 18-25 the separation is 50/50, but it can be related to the desire for mutation studies when planning to have children.



Graph 9. The willingness of people to pay for the genome research, the geographical location dependence

Of course, the survey was accepted by the majority of respondents from St. Petersburg or Moscow. But even if one analyzes at the preferences inside the region type, it can

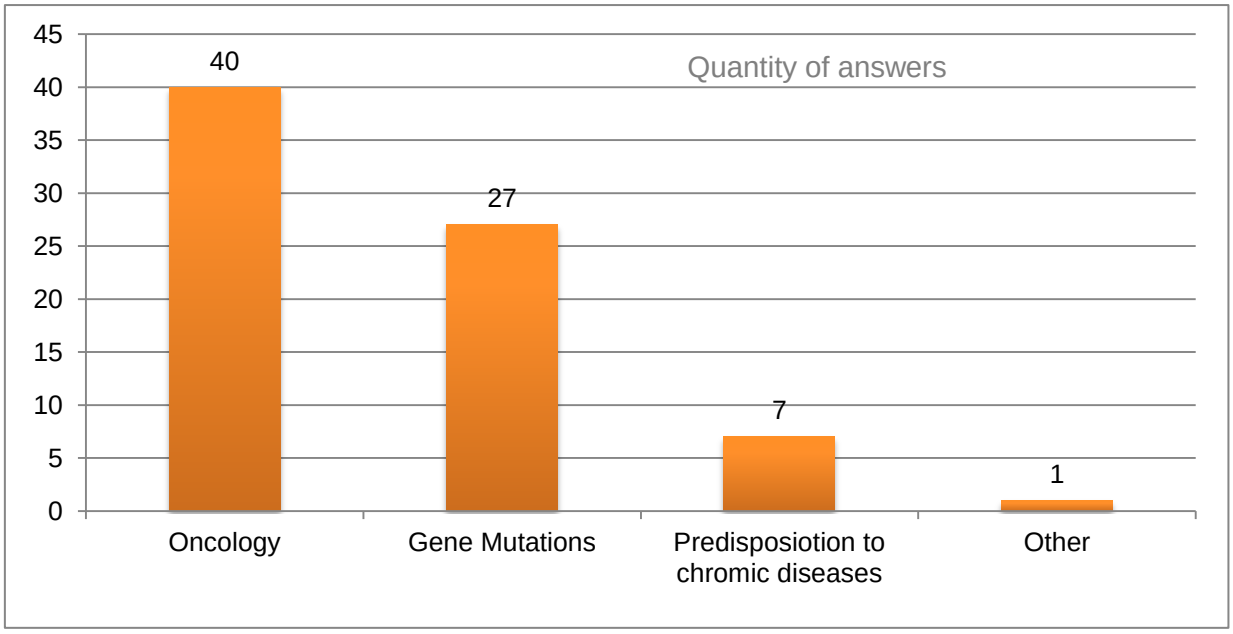
conclude that the smaller the city - the less willingness to pay.



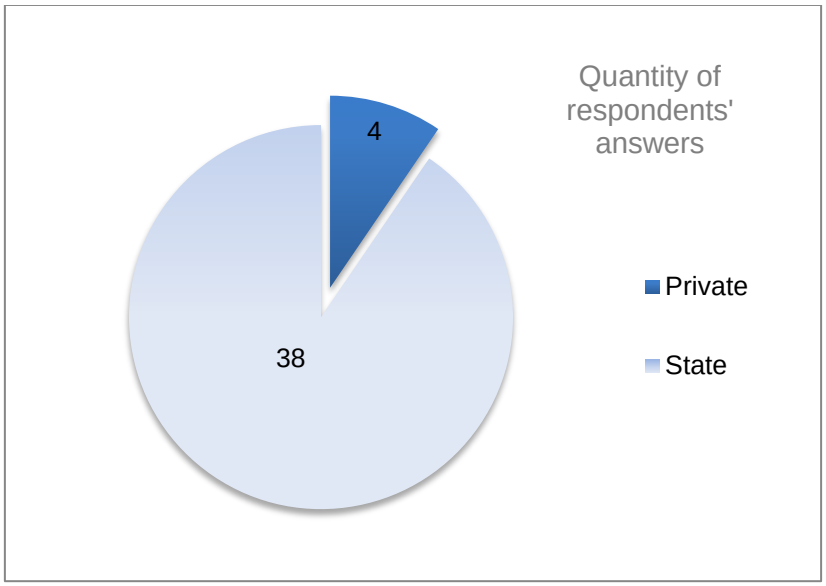
Graph 11. The willingness of people to pay for the genome research, the average monthly income dependence

An interesting conclusion is that all respondents with low income would refuse to pay, but all respondents with high - agreed. In principle, this is logical, for a person with a good income $ 3,000 is not such a huge amount to refuse to know everything about yourself. At the same time, a greater number of respondents consider that such a test should cost no more than $ 500.

When identifying an area that would be of interest, an important role is played by oncology. Graph 12 shows how the respondents were interested in the application. At the same time, 36 respondents (even those who are not ready to pay), said that they would prefer not a full research but a testing for some area for specific task. At the same time, people would prefer to do such tests not in commercial laboratories, but in state centers (Graph 13), which proves that Russian people generally trust the state programs in general.



Graph 11. Respondents' interest in the field of test application



Graph 12. Respondents' preference in the place of research

5 RESULTS AND DISCUSSION

5.1 Prediction of genome research on Russian market

Sequencing the genome is the right way to learn about yourself: good and bad things. Genetic predispositions and risks, features and potential diseases - the determination of the nucleotide sequence of DNA and its subsequent interpretation will tell more than all the analyses known before. The results of sequencing - the most detailed instruction for

the doctor on the treatment of a specific patient, designed to ask the world's diagnostics an astounding vector of development. After all, when in one medical file all diseases are prescribed at once - and even those that have not yet shown themselves - the doctor can only choose consistent goals and treat.

The research showed that the international market has significant development in this direction and many Russian experts are monitoring new technologies. Over the past 5-7 years, the technology has made great progress, and the time that it needed for make the test and the cost of research have been reduced from tens of thousands of dollars to 1,000-3,000 US dollars for full genome research. All this created favorable factors for the development of the market from a commercial point of view.

The Russian market is now a little frozen. Locally developed equipment and launching it to the mass using is already outdated and despite the fact that somewhere else it is used (according to the data of tenders and experts) is soon will go to the archive due to no economic performance.

News about new Russian developments remains only like news and do not have access to a practical market. Although within the framework of the modern policy of import substitution, funds can be allocated and projects can be forced to complete. But there is some theory of experts that it is more important for the government to launch not progressive developments and technologies, but simple and massive things that are used daily in medicine in order not to depend on foreign supplies.

In any case, sooner or later the Russian market of gene research will move into a medical area and will be widely distributed. Forecasts of experts say that from 5 to 15 years are necessary for the Russian market to put technology of genomic sequencing into mass use.

5.2 Factors of influence on genome research development in Russia

A significant development will be if these tests reduce the cost and are included in the program of mandatory insurance. The table 13 shows the factors and degree of their influence on the development of the trend on the basis of theoretical statements and the results of research.

Theoretical statement	Level of influence, comments
International market development	Strong influence, the rapid development of the technology market on the one hand gives new opportunities to the market, but on the other, creates such a problem as the rapid obsolescence of equipment and technologies.
Common Russian market Features	Strong influence - the backlog in technology and financing makes Russia lag in the direction of full genome research, but now there is a real chance to launch these projects, taking into account the favorable experience in foreign markets.
Market volume and the trend of changes	Not a certain level of influence. The volume of the Russian market is in principle large, because the country is large with a huge population. The definition of the demand itself will evolve depending on which way Russia will go - if it enters into mandatory medical research, and then the market will be very large. If the trend is to let people themselves pay for such gene research, then the market growth will not be so rapid, but will proportionately be depended from the cost of the test - the lower the cost, the greater the demand.
Problem factors for development	One of the main problem factors, that most experts and theoretical applications indicate is registration – the procedure of registration of the medical device taking around 2 years can force to situation that when a company is ready to start-up the promotion and sales of equipment on market, this equipment has become obsolete. Now the issue of registration is actively discussed at the state level and everyone hopes that soon this issue will be resolved. Eliminating this problem can significantly reduce this impact on the development of the market.

	Also, the problem of personnel for the decoding of genomic studies is widely discussed - this problem greatly affects the cost of the test and no prerequisites have been found to solve this problem.
Features of financing – state politic	Strong influence. Of course the main factors are the features of financing and budget allocation. Here, Russia can go for two ways (include in insurance or not) with an equivalent probability. But also the cost of the test can significantly affect the decision of the state.
Features of financing – individual readiness for pay	In general, people are ready to pay for such research mostly in large cities and if they have high incomes. Therefore, the market for commercial research has real opportunities for growth, especially if the promotion and information of the population were wider.

Table 13. The influence of theoretical statements on the development direction

In a more general way, a PEST analysis was used to analyze the macro environment, the results of the research in PEST model are shown in Table 6.

Group	Level	Comment
POLITICAL		
import substitution policy	Middle	So far there are no special prospects for local development; the market is oriented towards foreign companies.
long registration at the state level	High	While a new product is registered, it may already become obsolete.
weak development of domestic new products	Middle	Program of the government for financing the development of essential goods.

ECONOMICAL		
economic crisis	Middle	Well, it happened, the value of money decreased, but somehow the country still lives and develops.
high cost of tests	High	Too expensive test price does not allow making it mass.
features of financing	High	The question of where to pay, from insurance, from the budget or personal money is very serious
not including gene therapy in the medical program;	High	The most important for the development of the market in the direction of medicine.
SOCIAL		
not informing the population about new opportunities;	Middle	It is important for the development of private sector, but at the macro level it can be not so important, because mass character will be only including it in the state program.
unavailability of the system to protect information about genome research.	Middle	While not so much research is not an important issue, when the mass character begins it will be possible to use the achievements of the foreign states.
TECHOLOGICAL		
rapid technological development	High	The market reaction for rapid technological change.
fast obsolescence of old technologies	High	Buying expensive equipment that may soon become obsolete.
inexpediency of using old technologies	High	Same.

requirement of special personnel of bioinformatics	High	Influence on the cost and speed of the test and on the possibility of its implementation.

Table 14. Evaluation of the factors of PEST analysis

5.3 Determination of genome research demand

The information about the current market and the volume of tests conducted is very different and can use completely different bases for determining.

Considering **Market of equipment** - new generation sequencers, there is information that the potential of the market is 1000 equities, 120 units have already been supplied, and only a small part of them is used.

Using the theory of market calculation, proposed by the experts during the interview, it is possible to determine the following volumes.

In the future, with a mass market expansion, sequencers must be located in each research institute for scientific research; plus, if this direction goes to the medical sphere, and will be a regular research for diagnosing diseases, then in every central district hospital.

According to business map of Russia, noted in Figure 6, 1812 Research institutes located throughout all regions of Russia were found. Of course, most of the percentage is occupied by Moscow, St. Petersburg and major cities.

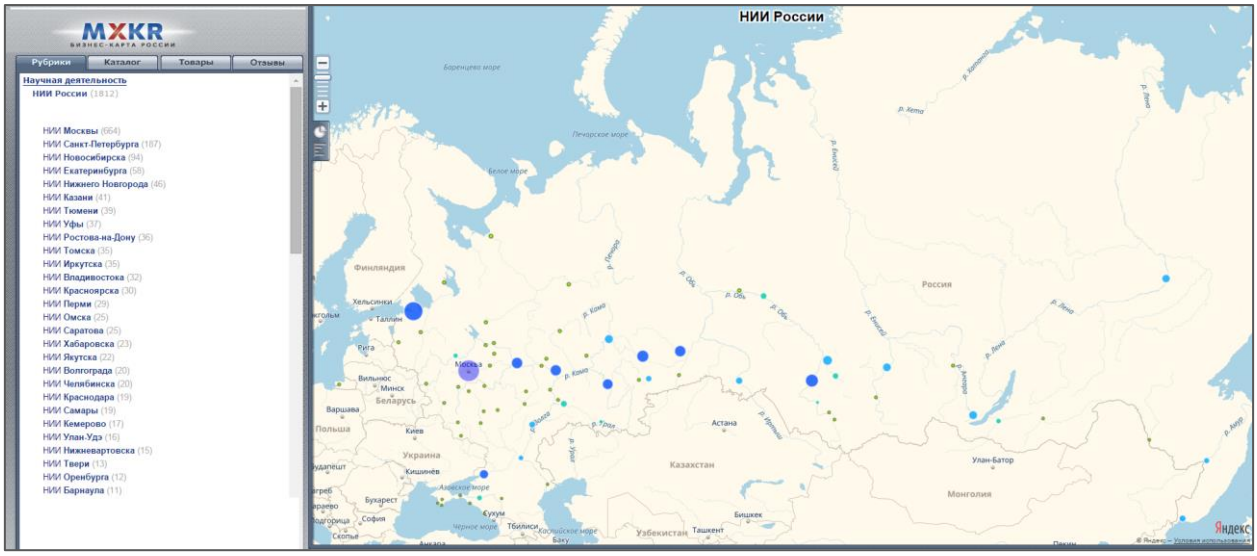
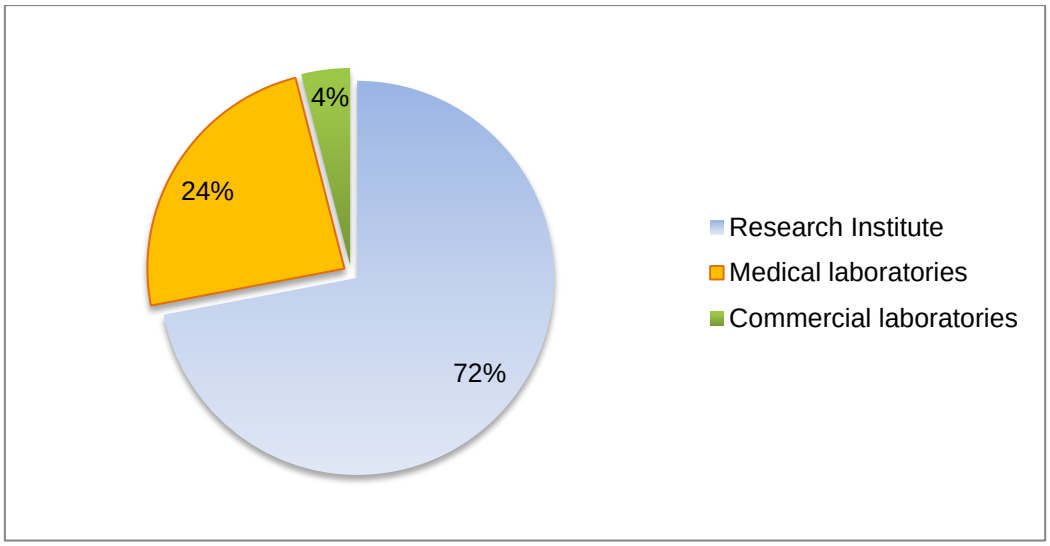


Figure 6. Russian business map of Research institutes

If in each Research institute there is 1 sequencer for carrying out researches in their study area, the market of scientific research will be **1800 units** of sequencers.

Further, the following theory is that if the sequencing of the genome passes into the medical field and becomes mandatory for the diagnosis of diseases, then the sequencer should be at least in large central district hospitals. According to previous submissions of the Case Company - in Russia there are around 600 such hospitals with departments of diagnostics, which can accommodate such large equipment. Thus, the market only for state use will be around of **600 units** of sequencers.

Now in Moscow there are about 10 private laboratories that offer a full of genomic sequencing, and 6 laboratories in St. Petersburg. If assume that with mass development in medical area in each major city (region center - 85 regions) there will be at least one commercial organization carrying out such tests, then to the total volume will be added around 100 sequencers. Thus, according to this theory, the volume of the market (and medicine and research) will be not less than 2500 sequencers (Graph 14).



Graph 13. Forecasting of Russian market structure for genome research equipment

If we try to determine the **volume** of **genome tests conducted**, according to the information from the literature, so far the sequencing of the genome has been conducted by about 60,000 -100,000 people in Russia (for whole time of sequencing history in Russia).

If genomic research is not included in the insurance program, and they will be available only for the personal payment of citizens, the development will not be so rapid. A study

of the people's experience shows that 22 out of 42 people are ready to pay for it; this is already a good result for the market forecast.

If the insurance program is changed, and the research is included in politics, then Russia can follow the path of America, where a genomic study has already been made to 5 million people (which contributes 1.5 % of the whole population) during five years. Thus, the growth in Russia with the purchase of an insurance program can be around 2.5 million genomic tests in 5 years – it is around 500,000 tests per year, which is five times more than now. The revealed tendency on purchases - annual increase in volume more than 100% confirms the given theory about the prospects of this market.

5.4 General results and suggestion to Case Company

As a result of the investigation, a possible demand for the equipment was identified - sequencers market and the direct quantity of full genome test in conditions of favorable influence of the studied factors. The volume of the market and the factors that influence the development of this market are predicted.

According to the opinion of the author, the market for genomic research is very promising and the future of disease diagnostics will necessarily include the genome test. But at the moment the market is very specific and there are not many players in the international market, and even more in the Russian market and as a rule these are large concentrators that require large investments in research.

In author's opinion, it will be difficult for the Case Company to enter into this market:

- as a manufacturer - without technology and special ties – the topic is too complicated;
- as a distributor of large companies - main players have already assigned roles.

But during preparing theoretical background was noticed active work on copying and improving technologies by the Beijing Genomics Institute, China. At the same time, in the process of communicating with the experts, almost nobody mentioned this Science Center and company as known on the Russian market. Case Company has great experience with working with Chinese companies and it would be good to study the activities of this center in more detail and the opportunities to apply their products on the Russian market.

The prospect of launching the market of medical research will begin at best in 5 years, according to common experts' forecasts and theoretical background. This direction of the work from commercial point of view can be evaluated as a distant perspective, which must be kept in mind and respond quickly to changes.

Factors that the company should keep track of if it wants to quickly become involved in commercial activities:

- Improvements of the technology of genome sequencing and reducing the cost of the test;
- When science does not simply decipher the genome, but also makes changes in the genome for improve human health;
- Launch of local Russian projects in this area (production of real products or reagents) under conditions of import substitution;
- Changes in financing conditions (including a genome tests in the insurance or budget program);
- Changes in the legislation on research activity and their connection with medical diagnostics;
- Reduction of registration deadlines;
- Popularization of genomic tests among commercial services.

The future is beyond genome research, but when it comes this future is difficult to predict, as it will depend on many factors. In order not to miss this opportunity it is necessary to keep this subject in view, but at the moment this topic cannot be a "cash cow” for the Case Company.

6 CONCLUSION

6.1 Description of the conducted research

Conducted research under Master's Thesis achieved the main objective - to understand how genome research will develop in Russia on macro level and how it will be interesting from the standpoint of commercial activity. Main research question, which was established for the research was forecasting of demand of Genome Research on Russia market from commercial point of view.

To fulfill the tasks, the author conducted an analysis of the macro environment and the influence factors by PEST analysis, using accessible theoretical materials, modern reviews, publications, interviews and articles available on the topic of genomic research on the international and Russian markets. Based on the results of this analysis, the main influences were determined in the fields of politics, economy, sociality and technology.

In the second step of the study, the author conducted her own research to confirm the influence factors, determining their level and the remaining open questions. For the study was used a combination of different research methods with the appropriate method of analysis.

The most suitable for the purpose of the study was Qualitative research method with division into secondary and primary information.

Secondary information was collected mainly based on the system of trading of Russian state institutions in recent years and related sources, like Registration system. The result of the analysis was obtained using the Secondary Information Analysis using the 'research question-driven' approach and the 'data-driven' approach.

The collection of primary information was also divided into three groups, depending on the type of respondents. To fully reflect the issue of the genome research from different areas, it was decided to receive opinions from three types of respondents:

- Experts involved in this question through interviews;

- Sales representatives of Case company through interviews;

- General public through on-line survey.

The analysis of the interviews was conducted using the Content analysis with the use of coding text and code matching technology. The analysis of the electronic survey was carried out using simple statistical analysis methods, but without the use of complex mathematical algorithms.

6.2 Suggestions for further research

In the frames of this research it could be advised to the Case Company, as mentioned above, to oversee the Asian market - China and possibly Japan and Korea. Their technology is developing very quickly and can replace or be much cheaper than the existing American huge companies.

Also, the Case Company mainly focuses on medical activities, in reality the topic of genome research is more widely used in the market of research institutes.

If the company still has the intention to move forward in the field of sequencers and reagents, then it is necessary to conduct research on the market of scientific institutes and research centers. Since the network of active distributors, based on the results of the survey was not suitable for the promotion of a new product, it will be necessary to conduct an analysis of the market of commercial organizations involved in the topic of sequencing the genome.

This research was carried out mainly with the forecast of positive changes. Forecast of the demand for genomic research made in view of the favorable development of all influenced factors. In future research it would be good to determine what will happen if these factors have a non-blocking effect. In this case, the basis for researching people's readiness for such tests is useful, which in future research could be expanded and also the focus could be more on commercial laboratories.

If go beyond the scope of this narrow topic, in the process of this study, several interesting topics were identified that were associated with genomic sequencing, but as separate directions:

- Exom research (selective research of the genome part)

  Interest in this exom research was traced both among experts and ordinary people, who did not even know what it is, but were ready to pay and conduct some of such tests. Oncology, for example, was the most popular area in

answers of people and experts.

- Biobanks - provision of services for storage of genomic data

  Many experts mentioned the issue of storage, data confidentiality and transfer. Now this direction has prospects in Russia - even Google is already engaged in something similar.

If the Case Company is interested in the development and study of other directions, these two topics can be interesting and promising for the Russian market, but additional information and new research is required.

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Appendix 1. List of suppliers of sequencers and reagents based on the results of state trading in 2012-2017

Name of company	Quantity of won tenders	Sum of contracts, rubles	Last date of participation in tender
ООО Компания Хеликон	44	81 039 940,94р,	18.09.2017 4:00
ООО 'ОРФК'	14	17 692 967,25р,	22.11.2016 9:00
Общество с ограниченной ответственностью «АЛЬБИОГЕН»	25	145 298 007,22р,	10.08.2017 5:00
Общество с ограниченной ответственностью "ГЛ ГЛОБАЛ"	24	22 558 190,00р,	22.12.2016 10:00
Общество с ограниченной ответственностью "Аламед"	21	40 716 319,49р,	25.04.2017 1:00
Общество с ограниченной ответственностью «ИнтерЛабСервис»	22	42 205 372,20р,	08.08.2017 4:00
Общество с ограниченной ответственностью "Агентство Химэксперт" (ООО "Агентство Химэксперт")	22	7 083 035,24р,	29.08.2017 3:00
Общество с ограниченной ответственностью "ДНК-Технология"	19	6 047 347,05р,	26.06.2017 4:00
Общество с ограниченной ответственностью «СкайДжин»	10	3 526 682,27р,	24.07.2017 6:00
Общество с ограниченной ответственностью "ВВВР"	6	8 565 875,76р,	02.11.2015 4:00
государственное научное учреждение Всероссийский научно-исследовательский институт ветеринарной вирусологии и микробиологии Российской академии сельскохозяйственных наук	7	4 962 279,38р,	26.02.2016 3:00
Закрытое акционерное общество "Геноаналитика"	3	2 227 668,20р,	28.08.2017 3:00
ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ "БИОВИТРУМ"	8	33 440 769,20р,	20.07.2017 3:00
ЗАО "Акрус"	5	14 104 408,00р,	26.07.2017 5:00
Общество с ограниченной ответственностью "НТЦ Прогресс-Технология"	7	7 647 900,90р,	04.12.2012 6:00
Общество с ограниченной ответственностью 'РУСХИМБИО'	6	16 998 766,10р,	21.07.2017 3:00
ООО "Диаэм"	2	2 067 426,00р,	07.11.2016 23:00
"Литех"	7	19 623 723,09р,	06.06.2017 2:00
Общество с ограниченной ответственностью «Балтмединцентр»	6	9 487 690,35р,	27.05.2016 5:00
«Брянскзооветснаб-ЮГ»	5	16 254 142,59р,	21.07.2017 3:00
ЗАО 'БиоХимМак Диагностика'	5	5 183 430,00р,	04.04.2017 3:00
Общество с ограниченной ответственностью «ГенЭра»	5	4 442 185,65р,	10.12.2015 10:00
Общество с ограниченной ответственностью "ПРОФИЛАБ"	5	4 296 965,24р,	19.08.2016 3:00

Appendix 2. Protocol of an interview with an expert

Comment: All interviews were conducted in Russian language; this protocol was translated into English specifically for this document and may contain inaccuracies in the translation.

Codes	Name of respondents: wished not to be published Specialization: microbiology Education: Candidate of Biological Sciences	Region (city):Saint-Petersburg Place of work: Private laboratory Area: clinical practice	Date of interview: 02.08.2017 Place: office Interviewer: Kazimirova E.
	What is your experience in genome research tests? *I am a Candidate of Biological Sciences; also I passed postgraduate studies in the Department of Molecular and Radiation Biophysics of the Petersburg Institute of Nuclear Physics, RAS. Area of my scientific and practical interests: cell biology, genetics, genome stability, genetic engineering, immunotherapy of oncological diseases using dendritic cells, cell cultures, autohemotherapy, genetic diagnostics, genotyping of humans, functional genomics.* *Now our laboratory center is widely represented in Saint-Petersburg and in other nearby regions. Routine DNA studies are performed using PCR. Recently we have established a mass spectrometer for research purposes.*		
RRC	**And do you have any experience of using sequencers in general and new generation sequencers in particular?** *I collaborated with the St. Petersburg Research Center on the decoding of the gene for research purposes. In principle, there are very few acting sequencers in the city, and even in Russia. But, as a rule, the centers for research work co-operate if they set an interesting task for them to study.*		
America Illumina Roche	**How do you evaluate developments on the world market?** *This is a very promising direction. Americans are very active in the topic of sequencing the genome, their development is quite progressive, a decade ago the task of complete decoding of the genome seemed impossible, then the development allowed it to be done, but millions of dollars were spent on it and years of working were needed. Now any person can do it. In developed countries, such tests are even put on stream. Very great success was achieved by the company Illumina - their sequencers occupy a large share of the world market. I have experience with this analyzer.* *Recently, Roche has been gaining momentum - they buy up all the exciting start-ups, as I think, and quickly realize them in action. They are also a pharmaceutical company - and genome research provides a great prospect for this - to monitor how the pharmacy will influence the treatment, taking into account all the specifics of the genome features.*		
China	**And what about the Asiatic scientists, have the Chinese not yet copied their**		

Illumina China	**technology?** *I heard about their development and copying, in my Illumina, but at international conferences or exhibitions I did not meet their developments. Of course, the Chinese are good fellows and quickly copy everything; I hink they certainly have something in their work that can substantially down the market. After all, the main problem why sequencing is not done for every patient is it's a significant cost.*
Expensive Bioinformatics Expensive	**And why are the tests so expensive?** *I think it's expensive, mainly because it's hard to decipher. After all, the result is not a ready report with a description of all the features of a person's genome, but a so-called genomic code. Specialists who do this are very rare and highly skilled. Bioinformatics is engaged in deciphering, but informatics or biologists are spread in our country (and abroad), and bioinformatics is a relatively new specialization. For such specialists the future is excellent - so if you do not know where your children are going to study, this is an excellent option for the future.* **And equipment and reagents - they are expensive?** *Here the method is even more important. Companies like Illumina and Roche have invested a lot of money in their development, so the technique on analyzers is very expensive. Of course they will put their costs in equipment and materials. But by the way, sequencers are essentially an open system and reagents can be used "not original", but simply the market of offers is so small that customers prefer to use what is supposed by the method.*
Skolkova America RRC Import substitution	**What do you think about Russian developments?** *I have met a lot of information about the beginning of development, in Skolkovo they are actively working on it. But to be honest now, the main titans are Americans and it will be difficult for Russians to catch up with them. But now actively seeking to replace all imports – maybe the government can and will stimulate Russian science centers in this direction.* **And I read an article about the promising Russian sequencer Nanofor, is not it?** *This is the previous generation, the so-called capillary sequencer. Yes, it can be used, but it's already past. In general, in Russia there was a boom about 5 years ago and many have installed analyzers of this type. But their technology is old for today. Many of them are still used, but it will go to waste because the sequencer of the new generation does the same work, but for less money and time*
Cost of test	**What do you think is the future of this direction?** *Insanely promising. The world is waiting for when the cost of full genome will cost not 2-3 thousand dollars as of now, but 100 dollars. Many developments have already announced such statements, but in practice have not yet met them.* **And in Russia?** *Now the Russian market has slowed down a bit. As I said, there was a boom when in the research institute installed these devices, but in fact they are not used, because they do not know how and for what.*

Private lab Government Medical program Registration	**I met information that in 2015 hundred and twenty devices were delivered across Russia, but only 20 of them work, it seems like the truth?** *Yes, something like that. True, recent years have increased the genome test service of private laboratories, but you know they do not always have their own equipment and often turn to the same scientific institutions on a fee basis.* *So there was an interview with the head of the laboratory network popular in Russia, where he very accurately reflected the mood in this area - everyone is waiting where these technologies and government factors will go in future, especially the acute issue of registration. Now many do not know if they need it. If the sequencing is included in the medical program, then this is one thing, if not, then the development will be quite different.*
Medicine usage	**And in your opinion is it necessary to use the genome research in medicine?** *If the test is conducted as it is now - I'm not sure. For many diagnostics, more routine and most importantly cheap PCR tests are suitable. Moreover, such a question arises - the person has learned everything about himself by genome test - and what's next. So I conduct such a test about myself, well, I know what kind of predisposition - and what's the use? I cannot do anything about it - science is just working on it. By the way - there is a very ineffective development on the make correction of the genome "Crispr" – I can send you information. When science comes to decipher and correct the genome, then it will be excellent.* *Although of course in some cases, widespread use in medicine would be useful, in my opinion oncology is certainly the main direction. But there is such a thing as research of exom - more pre-study of the genome, it's faster and cheaper, this practice is more real in my opinion.* *If genomic researches become available on the prescription of a doctor, this could simplify many activities, like treatment, in the course of oncology, for example.*
People to pay Expensive	**And if they are not included in the medical program, are people ready to pay?** *Judging by the fact that the supply in the market is growing – yes. Certainly not in such a mass version, because the research is expensive, but there are always well-off people who want to know everything about themselves.*
Market Medical market Medical program	**How do you think we can determinate volume of the equipment market and the market for research?** *Well here it is necessary to divide into the research market and the medical market.* *In a prospective forecast, each research institute with a corresponding specialization should have a equipment. Here we are talking not only about human DNA, but also animals, bacteria and other – for example now actively using this theme in population research (to know where and where people are moving).* *If the sequencing is included in the medical diagnostics program, then we can say that every large laboratory (at least central in the region) will need to have it - that's how to calculate.*

Appendix 3. Report on the study of respondents of the group "Ordinary People"

Comment: The survey and basic system reports were conducted in Russian language; this report contains is a translation and search of results for this survey.

Date	Age	Place of residence (city)	Position/ specialization	Average monthly income level	Are you familiar with the concept of sequencing of the genome?	Are you ready to pay $ 3,000 to fully decrypt your genome and know about all the predispositions?	How much do you think should such a test cost in USD (not more than)?	If there is not a possibility of full research but to study only parts of the genome associated with a certain area (eg predisposition to breast cancer, or mutation gene), it would be interesting	Which areas are most interesting?	Would you prefer to do such a test in a private clinic or state?
10.10.2017	35	SPB	Office worker	Middle	Yes	No	500	Yes	Oncology	State
11.10.2017	30	SPB	Scientist	Low	No	No	500	No	Oncology, Mutations	State
13.10.2017	25	SPB	Employee of the budgetary sphere	Middle	No	No	100	Yes	Oncology, Mutations, Releted	State
10.10.2017	18	Sochi	Student	Middle	No	No	500	Yes	Mutations	State
16.10.2017	42	Moscow	Office worker	Middle	No	No	500	Yes	Oncology, Mutations, Releted	State
17.10.2017	72	SPB	Pensioner	Middle	No	Yes	1000	Yes	Oncology, Mutations	State
18.10.2017	20	SPB	Student	Low	No	No	100	Yes	Oncology, Mutations	State
19.10.2017	52	Moscow	Office worker	Middle	Yes	Yes	500	Yes	Oncology, Mutations	State
20.10.2017	42	SPB	Office worker	Middle	No	No	1000	Yes	Oncology, Mutations	State
21.10.2017	36	S SPB	Business owner	Middle	No	Yes	500	Yes	Oncology	State
22.10.2017	19	SPB	Student	Middle	No	Yes	1000	Yes	Oncology	State
10.10.2017	42	Novgorod	Office worker	Middle	No	No	100	Yes	Oncology	State
24.10.2017	47	Novgorod	Technical worker	Middle	No	No	500	Yes	Oncology, Mutations	State
17.10.2017	35	Sochi	Office worker	High	No	Yes	1000	Yes	Oncology	State

17.10.2017	36	Sochi	Office worker	High	Yes	Yes	500	Yes	Oncology	State
17.10.2017	32	Pskov	Employee of the budgetary sphere	Middle	No	No	1000	Yes	Oncology, Mutations	State
10.10.2017	30	Novgorod	Technical worker	Middle	No	Yes	100	Yes	Oncology	State
10.10.2017	28	SPB	Office worker	High	No	Yes	500	Yes	Oncology	State
24.10.2017	26	SPB	Employee of the budgetary sphere	Middle	No	No	1000	Yes	Oncology	State
24.10.2017	23	SPB	Office worker	High	No	Yes	500	Yes	Oncology	State
10.10.2017	49	Pskov	Office worker	Middle	No	No	100	Yes	Oncology, Mutations	State
10.10.2017	52	SPB	Employee of the budgetary sphere	Low	Yes	No	500	No	Oncology, Mutations, Releted, Other	State
10.10.2017	67	SPB	Pensioner	High	No	Yes	1000	Yes	Oncology	State
10.10.2017	58	SPB	Business owner	Middle	No	Yes	500	Yes	Oncology, Mutations, Releted	State
24.10.2017	23	Krasnoyarsk	Office worker	Middle	No	Yes	1000	Yes	Oncology, Mutations, Releted	State
24.10.2017	47	SPB	Office worker	High	No	Yes	500	Yes	Oncology, Mutations	State
24.10.2017	32	SPB	Office worker	Middle	No	No	1000	Yes	Oncology, Mutations	State
24.10.2017	35	Moscow	Technical worker	Low	No	No	500	Yes	Oncology, Mutations	State
24.10.2017	48	SPB	Business owner	High	Yes	Yes	1000	Yes	Oncology, Mutations	State
24.10.2017	67	Pskov	Pensioner	Middle	No	No	100	Yes	Oncology	State
24.10.2017	45	SPB	Office worker	High	No	Yes	500	Yes	Oncology, Mutations	State
24.10.2017	31	Pskov	Office worker	Middle	No	Yes	500	Yes	Oncology, Mutations	State
10.10.2017	58	SPB	Business owner	Middle	No	Yes	500	Yes	Oncology, Mutations, Releted	State
18.10.2017	26	Krasnoyarsk	Office worker	Low	No	No	1000	Yes	Oncology, Mutations, Releted	State

24.10.2017	24	Krasnoyarsk	Office worker	Middle	No	Yes	500	Yes	Oncology, Mutations	State
24.10.2017	47	SPB	Office worker	High	No	Yes	500	Yes	Oncology, Mutations	State
18.10.2017	32	SPB	Office worker	Middle	No	Yes	500	Yes	Oncology, Mutations	State
24.10.2017	35	Pskov	Technical worker	Low	No	No	500	Yes	Oncology, Mutations	State

Summary conclusions

Age group	Ready to pay	Not ready to pay	TOTAL
18-24	4	4	8
25-34	5	6	11
35-49	7	8	15
Older then 49	6	2	8
TOTAL	**22**	**20**	**42**

City group	Ready to pay	Not ready to pay	TOTAL
Moscow, SPb	16	10	26
Big city	4	4	8
Small town	2	6	8
TOTAL	**22**	**20**	**42**

Income group	Ready to pay	Not ready to pay	TOTAL
Low	0	8	8
Middle	11	12	23
High	11	0	11
TOTAL	**22**	**20**	**42**

Desired price of the test	
Cost/test	Quantity of answers
$100	7
$500	21
$1000	14
TOTAL	**42**

Area of interest - quantity of answers	
Area	Quantity of answers
Oncology	40
Gene Mutations	27
Predisposiotion to chromic diseases	7
Other	1

Place of test	
Place	Quantity of answers
Private	4
State	38
TOTAL	**42**